Exhibit P-2

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4. ***Memarzadeh F, "Letter To The Editor: Active warming systems to maintain perioperative normothermia in hip replacement surgery" Journal of Hospital Infection (2010), doi:10.1016/j.jhin.2010.02.006***

This study (a copy of which is attached at Annex 9) noted:

"The squame plots show that particles are cleaned away from the patient by the airflow from the laminar diffuser no matter if the forced air warmer is on or off. The percentage of squames deposited on the patient was zero both when the forced air warmer was on or off."

"NIH concludes that in both scenarios, there is zero percent deposition on the patient for the contaminant sources and the heat generated by the patient provides some protection."

"When the forced-air warmer is operating, the downward velocity from ceiling laminar diffuser is slightly less strong than when it is off."

"Forced-air warmers seem to cause minimal disruption to laminar airflow systems that help protect the surgical site from contaminated particles sourced from surgical staff".

"This investigation validates Moretti et al's conclusion that forced-air warming technology does not increase the risk of surgical wound infection."

The Falsity of the Offending Statements (Contamination)

The Offending Statements (Contamination) were clearly intended to convey, and will have conveyed, to any one reading them, including Arizant's customers, that the use of the Bair Hugger forced air warmer in operating theatres increases the risk of infections because they are a source of contamination or infection. These Offending Statements (Contamination) can have no other coherent meaning and this meaning is false.

Forced air warming and Arizant's Bair Hugger® system are not a source of contamination or infection and do not increase the risk of infection. As already noted above, there have been many studies documenting the clinical benefits of forced air warming and none has identified forced air warming as the source of SSIs, and one study specifically found a reduction. As a result of this evidence, forced air warming had sufficient substantiation to be recommended by NICE and that is so despite your very selective quotations from the NICE Guidelines in the Advertorial which appeared in the Operating Theatre Journal intended to suggest otherwise.

Our client relies on the following findings from published articles and studies to demonstrate the falsity of the Offending Statements (Contamination) and in support of the fact that forced air warming does not increase the risk of surgical site infections or contamination:

1. ***Hall, A, T. Teenier, et al. (1991) "Bair Hugger does not increase microbial contamination in the operating room". Dallas, University of Texas Southwestern Medical Center Department of Anaesthesiology and Microbiology: 1-14.***

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This study conducted microbial surveillance in twenty cases randomly assigned to receive patient warming with or without the Bair Hugger® system. It concluded that *"The Bair Hugger does not increase microbial contamination in the operating room"*.

2. ***Zink, R.S. and P.A. Laizzo (1993) "Convective warming therapy does not increase the risk of wound contamination in the operating room" Anesth Analg 76(1): 50-53.***

   This study was designed to determine whether the use of convective warming therapy increased the risk of wound contamination. It concluded that *"convective warming therapy, when appropriately applied, does not increase the risk for airborne bacterial wound contamination in the operating room"*.

3. ***Sharp, R. J., T. Chesworth, et al (2002)*** **(already cited above).**

   We repeat the quote from the Abstract of the report: *"suggest that the patient warming system does not influence bacterial counts at the operating site in an ultraclean air-ventilated theatre ...."*.

4. ***Huang, J. K, E. F. Shah. et al. (2003) "The Bair Hugger patient warming system in prolonged vascular surgery: an infection risk? Crit Care 7(3): R13-16.***

   This study analysed the bacterial content in air and wound specimens collected during surgery in 16 patients undergoing abdominal vascular prosthetic graft insertion procedure, using the Bair Hugger® patient warming system. It concluded that use of the Bair Hugger® system *"does not lead to increased bacterial contamination of the operating theatre atmosphere, and it is unlikely to affect the surgical field adversely"*.

5. ***Morettl, B., A. M Larocca, et al (2009)*** **(already cited above).**

   Again, as quoted above, the study found that *"In light of the results reported here, the Bair Hugger system does not seem to pose a real risk of nosocomial infections...."*

In relation to your quotations from the article entitled *"Forced-Air warming: a source of airborne contamination in the operating room?"* Albrecht, Leaper and Gauthier, Orthopedic Reviews 2009 volume 1, we note that this paper was both sponsored by Augustine and has an employee of Augustine as a co-author. Therefore, its findings are questionable and cannot be regarding as being of evidential value. In any case, we repeat that independent studies as referred to above have shown that the Bair Hugger® system does not increase bacterial contamination in the operating theatre.

The first part of the Offending Statements (Contamination) cite an unpublished article entitled *"Forced Air Warming Blowers – an Evaluation of Filtration Adequacy and Airborne Contamination Emissions in the Operating Room"*, which we understand (from a list of Clinical Research produced by Scott Augustine in March 2010), is also authored by Albrecht, Leaper and Gauthier but together with others. It is impossible to fully respond to these claims without being able to review the article itself and without knowledge of the methodology utilised in conducting the studies and given your reliance on it **we request that you provide a copy by return.** Nonetheless, we make the same point in relation to its value given the relationship between the authors and Augustine and also note the following:

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- the Bair Hugger® blowers are not sterile and are not intended to be. That does not mean that they increase the risk of bacterial contamination.

- the claim that "some" blowers were emitting 300 million germ-size particles per hour" is scientifically meaningless and misleading. It attempts to conflate particles with fomites in the mind of the reader and makes no comparison with what is normal in operating theatres and published theatre standards. The Bair Hugger® system in fact removes particles from air with the proper operation of its filters. We can comment further on this when you have provided the article.

- the measure of particles taken at the end of the hose is used to imply that there is a risk of blowing these "airborne contaminates around the operating theatre ***or surgical site***" (our emphasis). The proper and recommended use of a Bair Hugger system couples a warming unit hose with a Bair Hugger single use warming blanket. Furthermore, in a typical clinical setting the warming blanket is covered by surgical drapes which carefully isolate the surgical field, creating yet another obstacle for any such transmission to occur.

In relation to your quotations from the NICE Guidelines, as mentioned above they are very selective and misleadingly quoted. You write, for example, "*microbial pathogens were detected in about 50% of the FAW devices when the air was sampled directly*" but you omitted (in what we can only assume is a deliberate attempt to mislead your readers) the beginning of that same sentence "*It is stated that normally filters should protect against entrained bacteria and fungus....*". Worst, you also omitted the conclusion of the sentence "*... and without perforated blankets*". The Avidan (1997) study being quoted here by NICE was precisely to check the efficacy of whether blankets and filters prevented contamination. Use without blankets is not normal use and would not be in accordance with our client's manufacturer's guidelines. We could go on in this vein, but perhaps it is simply sufficient to point out that having considered all the studies referenced in pages 372 to 374 of the NICE Guidelines, NICE concluded (page 376):

> "*Although many potential sources of adverse effects can be identified, there does not seem to be empirical support that indicates that warming systems increase the risk of infection if properly used. FAW systems are naturally built to eliminate bacteria. Similarly, FAW systems if properly used by following the manufacturer's instructions could prevent clinicians from causing any harm or injury to their patients.*"

Breach of CAP Code

You may be aware that the CAP Code, administered by the Advertising Standards Agency, applies to non-broadcast marketing communications in the United Kingdom. Clause 2.1 of the CAP Code states that all marketing communications should be legal, decent, honest and truthful. As the Advertorials contain certain Offending Statements, it is Arizant's position that the Advertorials are in breach of this requirement of the Code.

In addition, the Advertorials appear to be in breach of the CAP Code in the following specific ways:

- Clause 23.2 of the CAP Code states that:

  "*Marketers and publishers should make clear that advertisement features are advertisements, for example by heading them "advertisement feature"*".

  As the Advertorials are advertisement features, your failure to make this clear in the relevant journals is a breach of this provision of the CAP Code. With all advertisement features, there is a risk that readers will see them as objective, independent comments. That is so here.

- Clause 3.1 of the CAP Code states that:

  "*Before distributing or submitting a marketing communication for publication, marketers must hold documentary evidence to prove all claims, whether direct or implied, that are capable of objective substantiation*".

  All of the Offending Statements outlined in this letter in relation to the Advertorials are of such a nature that, if true, they ought to be capable of objective substantiation. However, it is Arizant's belief that you do not hold documentary evidence sufficient to prove the claims made in these statements. It is clear that various of the statements are made on the basis of the Video (produced by Augustine and not under proper experimental conditions). The *Albrecht, Leaper and Gauthier* (2009) article (sponsored by Augustine) and the as yet unpublished article by the same authors (with others) will also not constitute objective substantiation in the light of the reputable evidence cited above. Indeed, the Albrecht (2009) article does not even make strong claims about the effect of forced air warming (FAW) on patient safety. In fact, it only raises doubts: "*the present study did not evaluate the link between FAW and SSI rates*" and "*particulate emission from FAW blowers **could, conceivably,** be deposited onto the surgical site*" (our emphasis). Even the authors are uncomfortable making claims as categorical as those found in the advertorial. And as mentioned there is no evidence (i) that Bair Hugger® system interferes with an Operating Room's laminar flow; nor (ii) that Bair Hugger® system contaminates the Operating Room so as to cause infection.

  If you are not able to provide sufficient documentary evidence for each of the Offending Statements within 14 days of the date of this letter, we will have no option but to conclude that no such documentary evidence exists.

- Clause 3.2 of the CAP Code States that:

  "*If there is a significant division of informed opinion about any claims made in a marketing communication they should not be portrayed as generally agreed*".

  The Advertorials published in Operating Theatre Journal in May 2010 clearly portrays your position in relation to the issues as "The Facts". Even if Arizant were to accept that there were differing views on the issues concerned (which, for the avoidance of doubt, they do not) your portrayal of your position as fact would amount to a breach of this clause of the CAP Code.

- Clause 8.1 of the CAP Code states that:

> *"Marketers may give a view about any matter, including the qualities or desirability of their products, provided it is clear that they are expressing their own opinion rather than stating a fact."*

As mentioned in relation to clause 3.2, the Advertorial published in Operating Theatre Journal in May 2010 portrays as fact what is, at best, one of a number of opinions in breach of this clause of the CAP Code. Any assertions that go beyond subjective opinions are subject to clause 3.1 of the CAP Code, requiring you to hold documentary evidence sufficient to prove such assertions.

Trade mark infringement

Arizant Healthcare, Inc, is the owner of UK trade mark number 1519268 (Bair Hugger device mark) and Community trade mark numbers 000183368 and 005837893 (Bair Hugger device and word marks) (the "**Trade Marks**") details of which are attached at Annex 10. The false and misleading statements contained within the Video are detrimental to the reputation of the Trade Marks and as such constitute trade mark infringement under section 10(3) of the Trade Marks Act 1994 and Article 9(1) (c) of the Council Regulation on the Community trade mark (207/2009/EC).

Conclusion

Given your operation in the same field, your relationship with Augustine and the existence of the studies set out at paragraphs 1 to 3 above (of which you must or should have been aware), we have advised our client that it is possible that it is entitled to commence proceedings against you in relation to the Offending Statements for, amongst other things, malicious falsehood and trade mark infringement and that it may be entitled to seek an injunction, damages and other relief. However, our client is prepared to give you the benefit of the doubt in relation to whether or not you were aware of or were reckless of the falsity of the Offending Statements up until the date of this letter, provided that you provide the undertakings as set out below.

The contents of this letter and the studies and articles referred to in it, however, put you on notice that the Offending Statements are false. Our client requires written confirmation of your undertaking by no later than 4pm on 7 July 2010 that you will:

1. not in the future publish or caused to be published the Offending Statements or any other false or misleading statements in relation to forced air warmers or our client's Bair Hugger® product, including by publishing links to any sites operated by any other person including such Offending Statements;

2. not in the future use any of the Trade Marks in a way which takes unfair advantage of, or is detrimental to, the reputation of any of the Trade Marks; and

3. immediately withdraw all Offending Statements (and links to sites containing Offending Statements) and cooperate fully with our client in reversing the damaging effects of the Offending Statements by issuing a statement agreed and approved by our client retracting the false and misleading comments made.

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In the event that we do not receive written confirmation of compliance with the above undertakings within the time stated, we are instructed to make a formal complaint to the Advertising Standards Authority in relation to the Advertorials, whilst at the same time reserving all of our client's rights in relation to the Offending Statements. In addition, if you publish or cause to be published in the future the Offending Statements or any other false or misleading statements in relation to forced air warmers or our client's Bair Hugger® product, we will advise our client that they are entitled to commence proceedings in the English courts for, without limitation, malicious falsehood. This letter would be evidence of your knowledge of the falsity of the Offending Statements and consequently, of your malice in making them.

Please be aware that our client will not hesitate to take legal action. As you may know from your supplier, it has already commenced action in Germany against Augustine and one of its distributors in relation to claims wrongfully made about Bair Hugger® therapy (including wrongful claims of the product increasing infections and contamination).

We look forward to receipt of the above undertakings.

We await hearing from you.

Yours faithfully

Dechert llp

Dechert LLP

cc: Nordic Surgical Limited
4 Brackley Close
Bournemouth International Airport
Christchurch
Dorset
BH23 6SE

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STATEMENT

I, Steve Hammant-Stacey, affirm the each of the following statement is true to the best of my knowledge:

1. I am the Managing Director of Nordic Surgical Ltd, an organization specializing in the distribution of medical devices. My home and place of business is in the United Kingdom.

2. Several months ago I had a conversation with Prof. David Leaper, a UK surgeon and former chair of the Surgical Infection Task Force of the National Institute for Health and Clinical Excellence. Prof. Leaper informed me at an infection control meeting that he had been approached by an employee of Arizant, Inc. and told that if he continued to conduct research regarding the contamination of Bair Hugger blowers he "should be careful of repercussions." He was also told that there might be legal repercussions for Scott Augustine and Nordic if we continued to promote the disruption of laminar flow story.

Dated: 2 July 2010

Signature

Name: Steve Hammant-Stacey

Address: Unit 22 Basepoint Bournemouth
Aviation Business Park
Enterprise Close
Christchurch, Dorset BH23 6NX

STATEMENT

I, Robin Humble, affirm the each of the following statements are true to the best of my knowledge:

1. I am president of the international division of Hot Dog International, LLC, a business located in the United States and specializing in temperature management products for use in hospitals. My home and place of business are in the United Kingdom.

2. During the last 18 months or more, I have had contact with Prof. David Leaper, a UK surgeon and former chair of the Surgical Infection Task Force of the National Institute for Health and Clinical Excellence. Prof. Leaper and his clinical colleagues have been conducting research regarding the possible bacterial contamination of forced-air warming ("FAW") blowers and the impact of the waste heat produced by FAW blowers on laminar flow ventilation systems.

3. Prof. Leaper's research in this regard has already been published in *Orthopedic Reviews*. Another article has been accepted for publication in the *American Journal of Infection Control*.

4. Recently Prof. Leaper informed me that he would no longer be involved in research regarding the contamination of FAW blowers or the negative impact of waste heat on laminar flow. At approximately the same time, Prof. Leaper informed me that Robert Buehler, an executive of Arizant, Inc., a manufacturer of FAW devices, traveled from the United States to meet with Prof. Leaper in the UK. Mr. Buehler, according to Prof. Leaper, offered financial assistance if Prof. Leaper would refocus his research to projects sponsored by Arizant.

5. Prof. Leaper informed me that he declined Mr. Buehler's offer, but that he would, instead, cease his research in the area altogether.

Dated: 20/6/2010

Signature

Name: ROBIN HUMBLE

Address: HARTWELL HOUSE, 7 SNEYD AV
NEWCASTLE, STAFFS, UK

J

SEP - 6 2000 K001149

D. Substantial Equivalence

The Bair Hugger® Model 750 Total Temperature Management® system is substantially equivalent in safety and effectiveness to the predicate device, the Model 505 Total Temperature Management system (K960167), currently manufactured and marketed by Augustine Medical, Inc.

Bair Hugger Model 750 Warming Unit and Bair Hugger Model 505 Warming Unit

Summary of Similarities

- Both devices have the same intended use and patient populations.
- The Model 750 unit has similar mechanical characteristics; it uses the same type of heater and blower unit.
- The output temperature ranges at each temperature setting are the same (the tolerances are tighter on the Model 750 unit).
- The over temperature safety system provides visible and audible warnings.
- Both devices are designed for use with all of the current Bair Hugger blankets and the 241® fluid warming set. No modifications have been made to the blankets or the 241 set.
- Both warming units can be used as a shelf, floor or table model, or attached to an I.V. pole or bed rail. In addition, the Model 750 unit can be attached to a rack or stand.

Summary of Differences

- The Model 750 unit incorporates software as part of the primary temperature control system.
- The Model 750 unit provides greater airflow.
- The Model 750 unit measures the temperature at the distal end of the warming unit hose and displays it on the control panel; the Model 505 unit calculates this temperature. Because of this, the Model 750 unit uses a different warming unit hose.
- The Model 750 control panel includes independent switches for *Standby* mode and each temperature setting; the Model 505 control panel has one temperature select switch which, when pressed, changes the temperature setting to the next setting in the sequence.
- The Model 750 control panel includes an LCD window that displays error codes; because it lacks software, the Model 505 unit does not have an error code feature.
- The primary over temperature sensor for the Model 750 unit is set to 47 ± 2°C and the secondary over temperature sensor is set to 53 ± 3°C. The primary sensor for the Model 505 unit is set to 53 ± 3°C.
- The Model 750 unit can include a collapsible or non-collapsible warming unit hose with a variety of storage options.

Substantial Equivalence Table

Parameter	Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit	Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit
Intended Use	Patient warming	Patient warming
Clinical areas for device use	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients	Operating room, recovery room, intensive care unit, labor and delivery, emergency rooms, ships, aircraft, EMT vehicles, accident sites, long-term care facilities, home health care and other areas where medical professionals warm patients
Intended patient population	Adult and pediatric patients	Adult and pediatric patients
Device positioning	Can be set on table, floor, shelf or other hard surface; attached to a rack or stand; clamped to an I.V. pole; or hung on a bed rail	Can be set on table, floor, shelf or other hard surface; clamped to an I.V. pole; or hung on a bed rail
Dimensions	13.5" x 9.5" x 10.5"	13" x 10" x 11"
Weight	@12.5 lbs	@11.5 lbs.
Materials	Plastic/metal	Plastic/metal
Warming unit hose	Detachable, flexible, fixed length or collapsible, washable, 2.5" diameter	Detachable, flexible, fixed length, washable, 2.5" diameter
Recommended filter change	Every year	Every 6 months or 500 hours of use
Temperature sensor	Shuts the heater off if damaged	Shuts the heater off if damaged
Temperature range (at nozzle)	Ambient to 45 degrees	Ambient to 46 degrees
Heat generated	1644 BTU/h (avg.)	1112 BTU/h (avg.)
Electrical requirements	20 Amp fused circuit	20 Amp fused circuit
Power cable	15' hospital grade	15' hospital grade
Airflow at comparable operating pressure	Up to 48 cfm (22.6 L/s)	Up to 30 cfm (14.2 L/s)
Air filter	HEPA	0.2µM
Motor	40 watt DC	Fractional horsepower, single-phase, AC
Heater	1600W resistive	850W resistive
Leakage current	Meets requirements of UL 2601 and EN 60601-1	Meets requirements of UL 2601 and EN 60601-1
Power consumption at 20°C ambient condition	Peak: 1650W Avg.: 800W	Peak: 1000W Avg.: 450W
Diagnostics	Over temperature and temperature output testing and calibration; and error code troubleshooting can be performed by biomedical technician. Upon power-up and mode change, the software performs self-test functions	Over temperature and temperature output testing and calibration can be performed by biomedical technician

Substantial Equivalence Table (cont.)

Parameter	**Augustine Medical, Inc. Bair Hugger Model 750 Warming Unit**	**Augustine Medical, Inc. Bair Hugger Model 505 Warming Unit**
Over temperature detection	Independent electronic circuit. Thermal cutoff shuts the heater off at preset high temperature of 47±2°C, measured at the end of the hose, plus an independent electronic system that reacts in the same manner and at the same set points as the SE device	Independent bulb and capillary. Thermal cutoff shuts the heater off at a preset high temperature of 53°C±3°C (127.4°F±3.6°F), measured at end of the hose.
Overcurrent protection	Dual input fused lines	Dual input fused lines
Alarm system	Over temperature: flashing red light with audible alarm, heater and blower shut down. Error condition: audible alarm, unit goes into *Standby* mode, error code displays in LCD window	Over temperature: flashing red light with audible alarm, heater shuts down.
Control circuitry	Microprocessor-based	Analog
Blankets Used	All Bair Hugger blankets (see next page for details)	All Bair Hugger blankets (see next page for details)
Blood/Fluid Warming System that can integrate with warming unit	Augustine Medical Model 241 system (see next page for details)	Augustine Medical Model 241 system (see next page for details)

Bair Hugger® Blankets- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same blankets as found in the predicate device, the Model 505 Total Temperature Management system. These blankets, listed below, are currently manufactured and marketed by Augustine Medical.

- Model 522 Upper body blanket (K903360)
- Model 525 Lower body blanket (K903360)
- Model 540 Torso blanket (K921165)
- Model 537 Small lower body blanket (K950416)
- Model 300 Full body blanket (K873745)
- Model 536 (K920432)
- Model 530 (K913734)
- Model 305 Chest access blanket (K920265)
- Model 315 Multi-access blanket (K950416)
- Model 310 (K950416)
- Model 650 (K952864)
- Model 655 (K952864)
- Model 610 Full body surgical (K950432)
- Model 110 Outpatient (K960167)
- Model 630 Sterile cardiac access (K964673)
- Model 645 cardiac (K913734)
- Model 555 pediatric full access (K913734) ✓
- International white blankets: Models 42268 (K903360), 42568 (K903360), 40068 (K873745), and 44068 (K921165)

Model 241 Fluid Warming Set- Substantial Equivalence

The Bair Hugger Model 750 Total Temperature Management system uses the same 241® Fluid Warming Set (K933726) as found in the predicate device, the Model 505 Total Temperature Management system. The 241 Fluid Warming Set is currently manufactured for and marketed by Augustine Medical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2000

Augustine Medical
c/o David Westlin
Director of Regulatory Affairs and
Quality Assurance
10393 West 70th Street
Eden Prairie, MN 55344

Re: K001149
The Bair Hugger® Model 750 Total Temperature
Management® System
Regulatory Class: II Two
Product Code: DWJ
Dated: July 19, 2000
Received: July 21, 2000

Dear Mr. Westlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for <u>in vitro</u> diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number: Not known

Device name: The Bair Hugger® Model 750 Total Temperature Management® System

Indications for use: The Bair Hugger® Model 750 Total Temperature Management® System is intended to prevent and treat hypothermia and provide warmth to cold or shivering patients. In addition, the Bair Hugger® Model 750 Total Temperature Management® System should be used whenever conditions exist that could cause patients to become cold.

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001149

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801-109) or Over the Counter Use ____

K

Creative Technology

CT Associates, Inc.

7121 Shady Oak Road, Eden Prairie, MN 55344-3516
Telephone: (952) 470-0166 Fax: (952) 942-0293
Website: http://www.ctassociatesinc.com

Measurement of retention efficiency of Bair Hugger® pleated gas filters

Submitted to:
Mark Albrecht
Augustine Biomedical and Design

Submitted by:
Mark Litchy
CT Associates, Inc.

June 10, 2009

Objective

To measure the retention efficiency of two types of pleated gas filters used in Bair Hugger® temperature management units as a function of particle size under typical operating conditions.

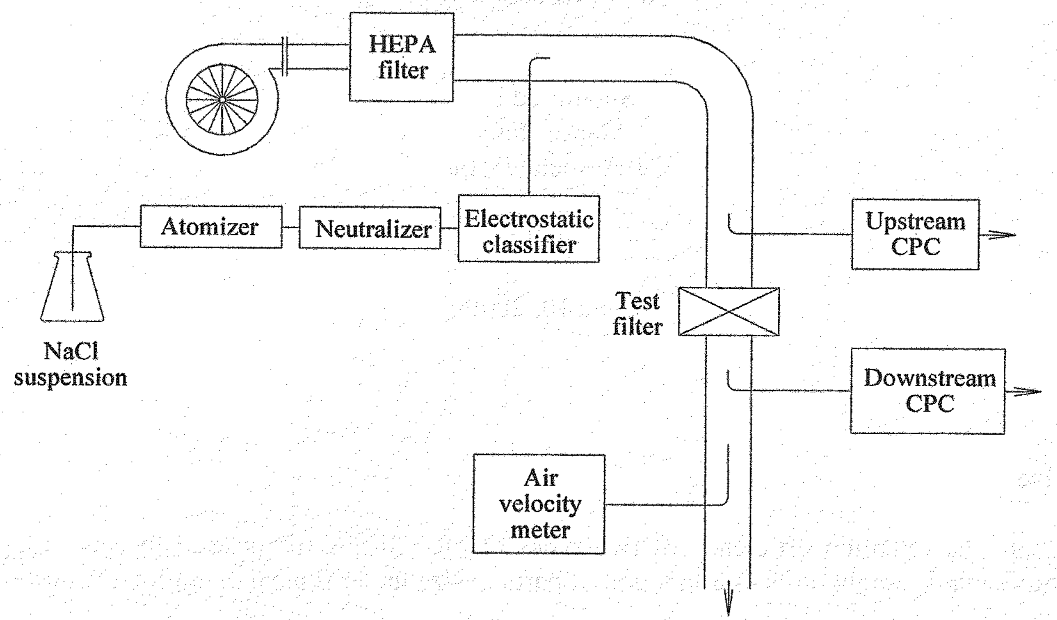
Experimental

Two types of pleated gas filters were tested in the system shown below. One was rectangular (750094 700 series) while the other was cylindrical (200708 Model 505). The filters were evaluated at flow rates of 45 and 30 scfm, respectively. The Model 505 filters came from two different lots, one containing brand new filters and one containing filters from an older lot that had been previously used (PN 200707C). The 700 series filters were all brand new filters from the same lot. Lot numbers were not available. A filter holder was constructed by Augustine Biomedical and Design to hold either filter type.

Measurements of retention efficiency were made at particle sizes ranging from approximately 0.025 to 0.50 µm. This size range allowed us to determine the most penetrating particle size (MPPS) for each filter type.

Monodisperse sodium chloride aerosol was used to challenge the filter media in the test system shown in Figure 1. In this system, 30-45 scfm of clean air into which the NaCl aerosol particles were injected was passed through the test filter. The NaCl particles were formed by first preparing a 30% NaCl solution. The solution was then vacuumed filtered through a 47mm 0.2 µm Nylon filter (Cole Parmer part no. 02916-34). The NaCl solution was then injected into an atomizer and dried to form a high concentration, polydisperse NaCl aerosol. The NaCl aerosol was passed through an aerosol neutralizer that exposed the particles to radiation from a Krypton-85 radiation source thereby reducing the charge distribution on the particles exiting the neutralizer to Boltzmann equilibrium levels. Finally, the aerosol was passed through an electrostatic classifier, which classified the particles according to their electric mobility diameter. Controlling the voltage on the collector rod in the classifier varied the size of the monodisperse particles exiting the classifier.

Figure 1. Schematic of test system



Simultaneous measurements of particle concentrations upstream and downstream of the test filters were made using two condensation particle counters (CPC). The CPCs measure all particles larger than approximately 0.010 µm in diameter. To ensure the background of the test was sufficiently low (<0.01 particles/cm^3), measurements were made both upstream and downstream of each test filter prior to each test without a test aerosol being generated. Then, the electrostatic classifier was set to produce a monodisperse aerosol of a given particle size and the concentrations upstream and downstream of the test filter were monitored for a minimum of four minutes and a maximum of ten minutes. This challenge time was long enough to capture sufficient data yet short enough to minimize loading on the filter. The voltage on the electrostatic classifier was then changed to generate a monodisperse aerosol of another size and upstream and downstream concentrations were measured. This process was repeated until six monodisperse sizes were tested: 0.025 µm, 0.050 µm, 0.100 µm, 0.200 µm, 0.300 µm, and 0.400 µm. Challenge concentrations varied from 3 to 400 particles/cm^3, depending on particle size.

Filter retention efficiency was determined by calculating the fraction of particles captured by the filter at each particle size. Periodically, measurements of the concentrations upstream and downstream of the filter housing were made without a filter in the housing to ensure that the CPCs agreed. The flow rate through each filter was measured using a pitot tube and manometer located downstream of the test filter.

Results and Discussion

Figures 2 and 3 present the retention efficiencies of five filters of each type as a function of particle diameter from the "New" filters. Figure 2 presents results from the 700 series filters, while Figure 3 presents results from the 505 series filters. Three different mechanisms play important roles in the removal of particles from gases by filters: diffusion, interception, and impaction. As particle size decreases, the rate of particle diffusion increases and hence the collection efficiency of a filter increases. As particle size increases, the effectiveness of particle capture by interception and inertial impaction increases and hence the collection efficiency of a filter increases. For intermediate particle sizes, on the order of 0.05-0.50 µm, none of these mechanisms are particularly efficient at capturing particles. As a result, gas filters have minimum capture efficiency at a size known as the most penetrating particle size (MPPS). For these two filter types the MPPS was approximately 0.2 µm and the retention efficiency at that size was 60-70%.

Figure 2. Retention efficiency as a function of particle size for the 750094 700 series filters at 45 scfm

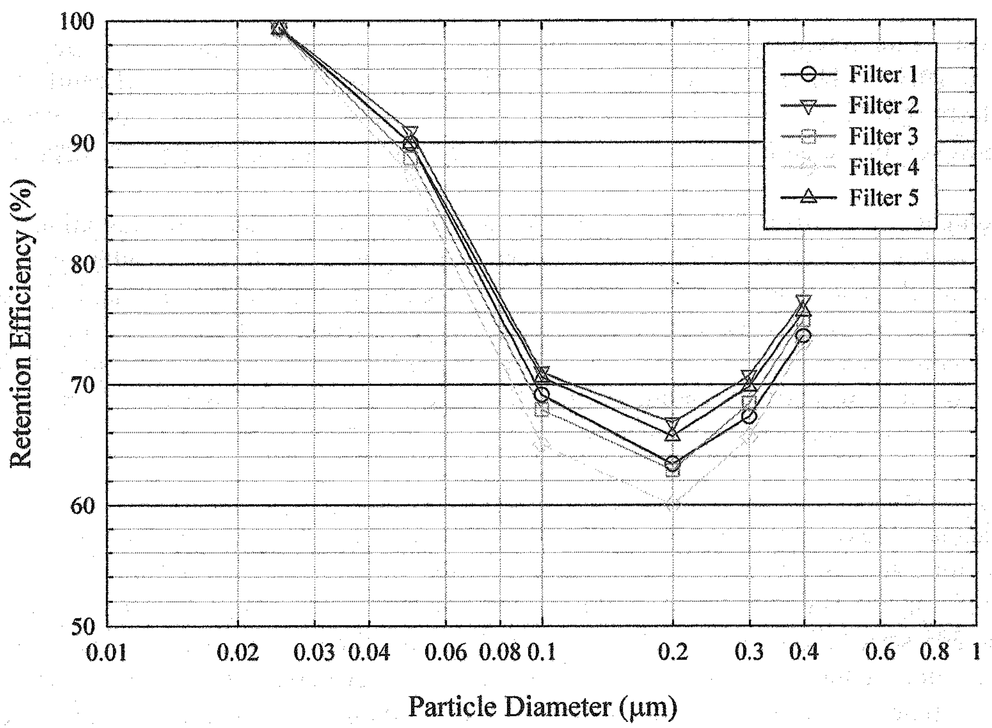


Figure 3. Retention efficiency as a function of particle size for the 200708 Model 505 "New" filters at 30 scfm

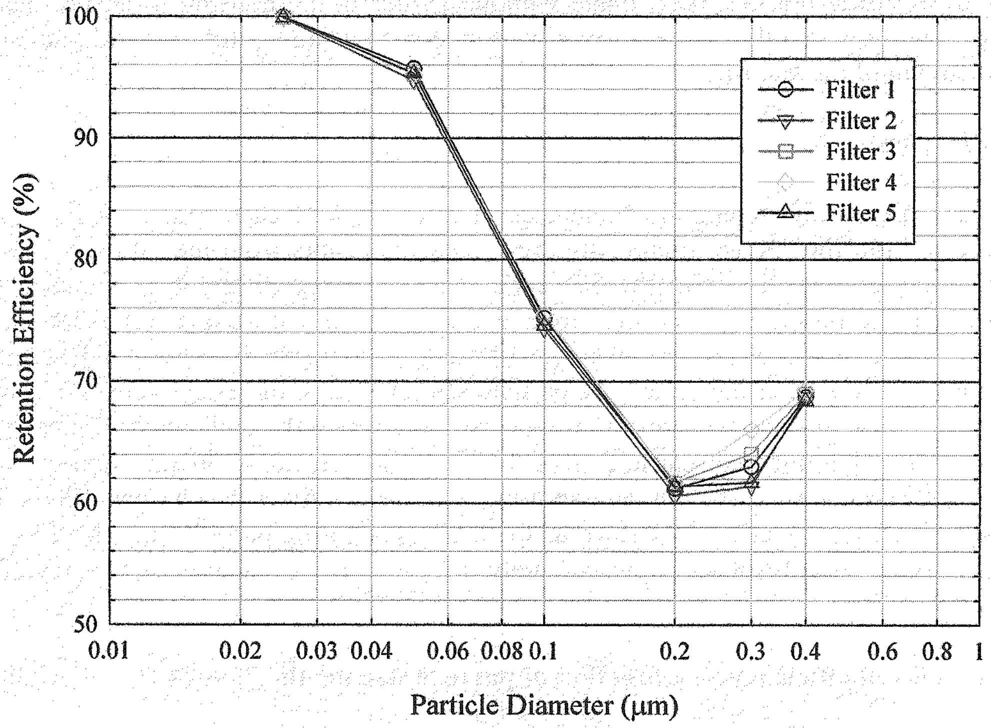


Figure 4 presents the retention efficiencies of four filters as a function of particle diameter from the "Used" older lot. The retention efficiency of the filters in this lot was significantly higher than those from the "New" lots. Like the "New" lots, the MPPS of the "Used" filters was about 0.2 μm. However, the retention efficiency of the "Used" filters at the MPPS was 90-96%.

Figure 5 compares the different filters by presenting the mean and standard deviation of the efficiencies measured at each particle size presented in Figures 2-4 for each filter type. The mean retention efficiencies at the MPPS were 61% and 64%, for the "New" 505 and 700 series filters, respectively, and 94% for the "Used" lot of 505 series filters. Clearly, the older filters were significantly more retentive than the newer filters. Filter particle removal efficiency typically improves with particle loading. Since the older filters were previously used, it is not clear whether the improved efficiency was the result of more retentive media or loading or both.

The collection efficiency curves of the "New" filters appear to be similar to each other except that the efficiency curve of the 700 series filter was shifted to left of the curve for the 505 series filter. Assuming that the filter media are identical, the difference in the retention efficiency curves may simply be due to the fact that the 700 series filter was tested at a 50% higher flow rate than the 505 series filter. A higher flow rate reduces the time that the smaller particles have to diffuse and thus reduces capture by diffusion. On the other hand, a higher flow rate means that larger particles are captured more efficiently since their larger speed will increase the efficiency of particle capture by interception and inertial impaction. This combination shifts the MPPS to a smaller size.

Figure 4. Retention efficiency as a function of particle size for the 200708 Model 505 "Used" filters at 30 scfm

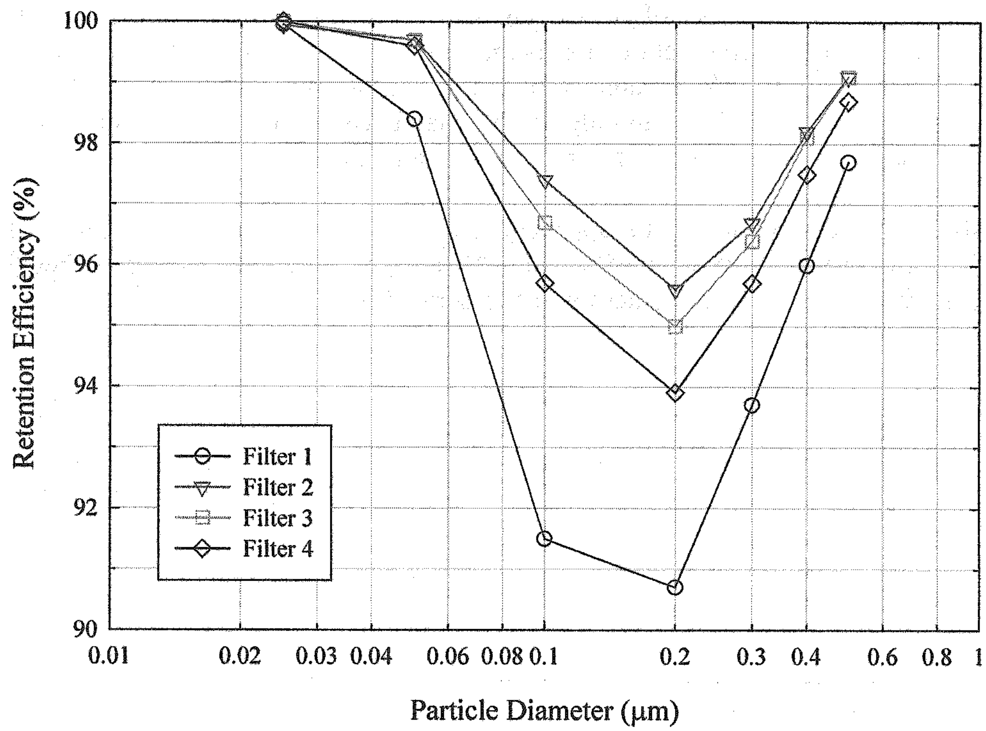
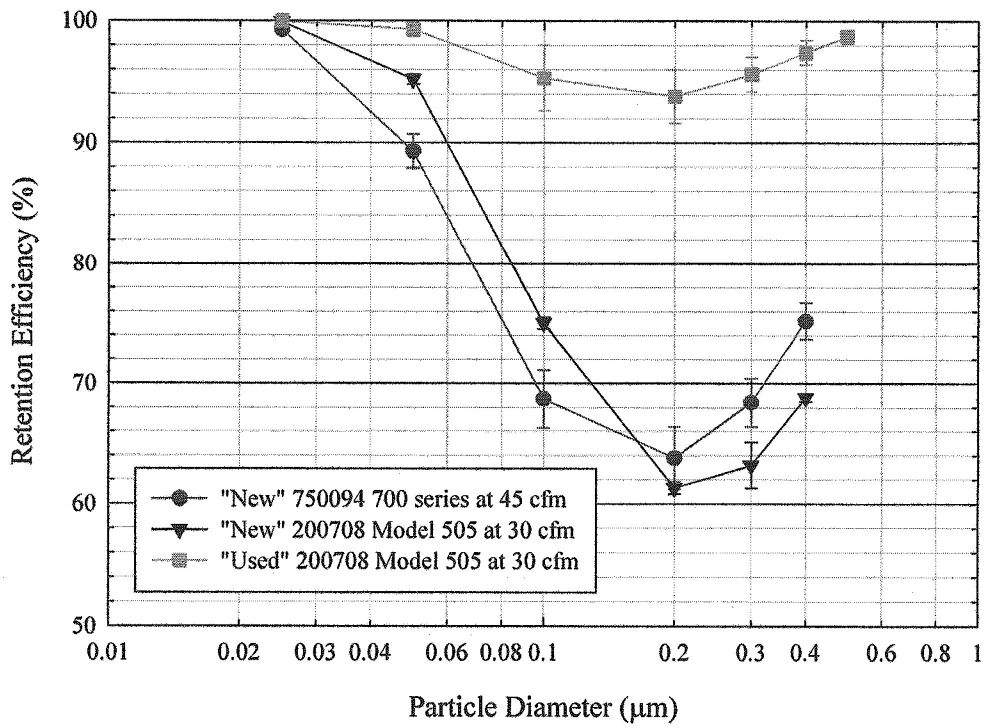


Figure 5. Mean retention efficiency for all filters as a function of particle size



Summary

The retention efficiency of two types of pleated gas filters (750094 700 series and 200708 Model 505) used in Bair Hugger® temperature management units were evaluated as a function of particle size. The Model 505 filters came from two different lots, one containing brand new filters and one containing filters from an older lot that had been previously used (PN 200707C). The 700 series filters were all brand new filters from the same lot.

The mean MPPS was determined to be approximately 0.2 µm for each lot of filters. Mean retention efficiencies at the MPPS were 61% and 64%, for the "New" 505 and 700 series filters, respectively, and 94% for the "Used" older lot of 505 series filters.

H: 510(k) Summary of Safety & Effectiveness

K964673

Safety JUN 26 1997

This 510(k) Summary of Safety & Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The device is a Class II device, System Thermal Regulating 74 DWG, Patient Warming System called the Bair Hugger® Total Temperature Management System® - Modification. The predicate device is the Bair Hugger Patient Warming System, Model 525 Blanket (K903360). The following summarizes safety issues related to skin surface warming devices and the measures to prevent these problems.

1. Summary of Safety:

A. Injuries to tissue: Cutaneous burns. Thermal injury is determined by a combination of temperature and time. Patients with ischemic limbs or extremely poor perfusion are especially susceptible to thermal injuries.

Prevention: The Bair Hugger Series 500 and 600's Maximum Heat Output (setting III at 43°C) do not provide temperatures high enough to cause burns to tissue. Performance testing demonstrated that by the time the air leaves the Bair Hugger Temperature Management Units, flows through the hose and is circulated through the inflatable Blanket placed over the patient, temperatures have dropped from 43°C to 41°C. These temperatures are well within the range of safety.[1,2]

Overtemperature condition: Bair Hugger Temperature Management Units temperature-out-of-range detection system is mechanical, using thermostats to detect over/under temperature conditions. The system triggers audible and visual alarms and shuts the blower's heating elements off when overtemperature conditions are detected.

Labeling: Labels affixed to each Bair Hugger Blanket next to the inlet port and packaged with each Bair Hugger Blanket read as follows:
"Contraindications: 1. Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury to ischemic limbs may occur.
2. Do not leave patients with poor perfusion unmonitored during prolonged warming therapy sessions."

B. Hyperthermia:

Warming treatment continued past the point of the patient reaching normothermia may eventually produce hyperthermia.[3]

Prevention: Instructions packaged with each Bair Hugger Blanket instruct the user to "Monitor the patient's temperature at least every 10 to 20 minutes."

C. Systemic Complications:

1. Prevention: Patient core temperature is continually monitored by clinicians during anesthesia with a device of their choice. The "Instructions for Use" packaged with each Bair Hugger Blanket states that patient temperature should be continually monitored with an appropriate device.

D. Other Safety Concerns:

1. Contamination. Airborne contamination from air blown intraoperatively across the surgical wound may result in airborne contamination.

Prevention of airborne contamination: All Bair Hugger® Blankets designed for use in the operating room feature a tape barrier which prevent air from migrating toward the surgical site. Additionally, air is filtered through a 0.2 micron filter. Two studies have concluded that the Bair Hugger 500 Series Units (that have the same air output specifications and the same filter density as the Model 600) do not increase the incidence of microbial or wound contamination.[4,5]

2. Summary of Effectiveness

The Bair Hugger Model 630 Cardiac Blanket effectively provides hypothermia treatment when used as part of a system with Bair Hugger Temperature Management Units.

Performance data show that the Model 630 Cardiac Blanket delivers air temperatures in the warming mode within the same specifications as the Bair Hugger Model 525 Blankets, using the same Bair Hugger Temperature Management Units.

Conclusion

The Model 630 Cardiac Blanket is constructed of the same materials as the Model 525 Blanket and other blankets currently on the market. The intended use of the Model 630 Cardiac Blanket is identical to that of the Model 525 Blanket. Therefore, because of the similarities to the predicate device, Augustine Medical believes this Modification does not raise any new safety or effectiveness issues.

Bibliography

1. Moritz AR, Henriques FC. The Relative Importance of the Time and Surface Temperature in the Causation of Cutaneous Burns. Am J Path 23:695-720, 1947.
2. Stoll AM, Green LC. Relationship Between Pain and Tissue Damage Due to Thermal Radiation. J Apply Phys 14:373-382, 1959.
3. Genauer, MB. Postoperative Heat Stroke. Anesthesiology 7:302-309, 1946.
4. Hall, A. Bair Hugger® Warmer Does Not Increase Microbial Contamination in the Operating Room. Abstract presented at the Post Graduate Assembly, New York Society of Anesthesiologists, New York, NY, December 1991.
5. Zink, RS. Convective Warming Therapy Does Not Increase the Risk of Wound Contamination in the Operating Room. Anesthesiology 77:A1093, 1992 & Anesth Analg, 1993:76;50-3.

Contact: Scott D. Augustine, M.D., CEO
Augustine Medical, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Scott Augustine, M.D.
CEO, Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, Minnesota 55344

JUN 26 1997

Re: K964673
Augustine Medical Bair Hugger® Model 630 Cardiac Blanket
Regulatory Class: II (Two)
Product Code: 74 DWJ
Dated: April 8, 1997
Received: April 9, 1997

Dear Dr. Augustine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for <u>in vitro</u> diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address"dsmo@fdadr.cdrh.fda.gov."

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

870.5900 - Thermal Regulating System - Patient Warming Blanket
DWJ-II

Indications for Use

510(k) number: K964673

Device name: The Bair Hugger® Patient Temperature Management® System - Modification: Model 630 Cardiac Blanket

Indications for use:

The Bair Hugger® Model 630 Cardiac Blanket is intended to be used to warm adult patients during cardiac surgery.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K964673

Prescription Use X
(Per 21 CFR 801-109)

or

Over the Counter Use ______

AUGUSTINE MEDICAL, INC.
6/25/97

M

N

Bair Hugger® Therapy

Product Specifications

TEMPERATURE MANAGEMENT UNITS

Bair Hugger® therapy temperature management units have become the standard of excellence in forced-air warming. They are small, lightweight and easy to use. All Bair Hugger temperature management units are designed to provide clinically effective patient warming at safe air delivery temperatures.

Temperature Management Unit - Model 505

Dimensions: 13" h x 10" w x 11" d (33 x 25 x 28 cm)

Weight: 13.6 lb (6.2 kg)

Filter: High-efficiency, 0.2 μm filter

Operating Temperature:
High: 43° ± 3°C (109.4° ± 5.4°F)
Med: 38° ± 3°C (100.4° ± 5.4°F)
Low: 32° ± 3°C (89.6° ± 5.4°F)

Device Rating:
110-120 VAC, 60 Hz, 9.5 Amperes
220-240 VAC, 50 Hz, 4.5 Amperes
100 VAC, 50/60 Hz, 10 Amperes

Certifications: UL 544, CSA C22.2 No. 125, IEC 60601-1-1, IEC 60601-1-2, EN55014, AS 3200.1990

Leakage Current: Meets regulatory standards for leakage current

Temperature Management Unit - Model 750

Dimensions: 12" h x 10" w x 13.5" d (30 x 25 x 34 cm)

Weight: 15.5 lb (7 kg)

Filter: High-efficiency, 0.2 μm filter

Operating Temperature:
High: 43° ± 1.5°C (109.4° ± 2.7°F)
Med: 38° ± 1.5°C (100.4° ± 2.7°F)
Low: 32° ± 1.5°C (89.6° ± 2.7°F)

Device Rating:
110-120 VAC, 50/60 Hz, 11.7 Amperes
220-240 VAC, 50/60 Hz, 7.2 Amperes
100 VAC, 50/60 Hz, 14.5 Amperes

Certifications:
EN 60601-1, UL 2601-1, CSA C22.2 No. 601.1, EN 60601-1-2

Leakage Current: Meets regulatory standards for leakage current

Arizant Inc., 10393 West 70th Street Eden Prairie, MN 55344, USA
Phone: 952-947-1200 • Toll Free: 800-733-7775 • Fax: 952-947-1400 • www.bairhugger.com

602381B 08/08

State of Minnesota
County of Hennepin

Affidavit Under Oath:

To Whom It May Concern:

We, the undersigned, are all former engineers of Arizant, Inc., the company that manufactures Bair Hugger®. A majority of us worked specifically on Bair Hugger models 505 and 750 forced air warming blowers. Collectively, we are the listed inventors on more than 100 patents held by Arizant, Inc.

<u>In our opinion there is no practical way to clean and decontaminate the air-flow path of forced air warming systems.</u>

In designing the Bair Hugger blowers, the following assumptions were made:

1. That the 0.2 micron inlet filter (which is <u>not</u> a HEPA filter) was adequate to filter the already clean air of the operating theatre, and
2. That any pathogenic organisms entering the blower would not survive the warm, dry environment inside the blower.

With the emergence of air-borne superbugs, these assumptions are no longer adequate.

- The inlet filtration of Bair Hugger blowers does not prevent contamination. The majority of blowers that we have cultured were contaminated with bacteria.
- Some forced air blowers emit large numbers of 0.3-0.5 micron particles. We have measured up to 50 million particles per hour blowing from the hoses.
- The warm, dry interior of forced air blowers does not kill all pathogens. According to published literature, many of the most worrisome organisms such as MRSA and Acinetobacter remain viable for extended periods in dry environments and have been cultured from forced air blowers.

Keith Leland

Randy Arnold

Scott Entenman

Mark Albrecht

Andreas Deibel

Subscribed and sworn to before me, this 16th day of July, 2008.

Susan Elaine Schaefer
[signature of Notary]

(SEAL)

Susan Schaefer

My commission expires: January 31, 20 10.

SUSAN ELAINE SCHAEFER
Notary Public-State of Minnesota
My Commission Expires
January 31, 2010

P

Karen Ray
Supplies Department
Rotherham District Hospital
Moorgate Road
Oakwood
Rotherham
South Yorkshire
S60 2UD

1st August 2008

Dear Ms Ray

Thank you for your inquiry related to a recent letter sent by Augustine Biomedical + Design (ABD) entitled "NICE patient-warming guidance (CG65) – potential violation of the Health Act and contamination of operating theatres."

As context, the letter's author, Dr. Scott Augustine, was founder of the company now known as Arizant Healthcare Inc., manufacturer of Bair Hugger® therapy. Dr. Augustine departed our company in 2002 and has been promoting a competitive product in recent years.

Dr. Augustine's letter contends that "The use of forced air may cause Trusts to inadvertently violate the Health Act and promote bacterial contamination of operating theatres." Actually, over the last 20 years forced-air warming has been used safely and effectively on more than 100 million patients worldwide. We are unaware of any research linking forced-air warming units as the source of a surgical site infection (SSI). On the contrary, maintaining normothermia with forced-air warming has been shown to *reduce* surgical site infections. Additionally, more than 100 studies have documented the clinical benefits of forced-air warming and maintaining normothermia.

Forced-air warming is the predominant patient warming modality and has been specifically named in major national SSI reduction initiatives including those that are part of the National Institute for Health and Clinical Excellence (NICE) "Inadvertent Perioperative Hypothermia" guideline in the UK, and the highly influential Institute for Healthcare Improvement's "5 Million Lives" campaign in the US.

The content in the ABD letter is misleading and often false. The attached information provides details on the statements from the letter along with additional information about the safe and effective use of forced-air warming. If you would like further information, please contact Arizant's UK Manager, Julian Biggs, at 07970 430302.

Sincerely,

Gary R. Maharaj

Gary Maharaj
President and Chief Executive Officer

Attachments

Facts Related to Forced-Air Warming and Clarifications Regarding a Letter Entitled: "NICE patient-warming guidance (CG65) – potential violation of the Health Act and contamination of operating theatres"

- A recent letter by Dr. Scott Augustine of Augustine Biomedical + Design (ABD) contends that "The use of forced air may cause Trusts to inadvertently violate the Health Act and promote bacterial contamination of operating theatres." It is our position that this contention is reckless and unfounded. It also discredits the enormous amount of work the NICE Guideline Development Group (GDG) put forth in creating a well-researched and extensively reviewed guideline.

- The GDG specifically explored potential "adverse effects arising from warming devices used for the prevention or treatment of inadvertent perioperative hypothermia" in section 10.4 of the full guideline published in April 2008. In their conclusions, they stated: "…there does not seem to be empirical support that indicates that warming systems increase the risk of infection if properly used. FAW [forced air warming] systems are naturally built to eliminate bacteria. Similarly, FAW systems if properly used by following the manufacturer's instructions could prevent clinicians from causing any harm or injury to their patients." (p. 376)

- Published research papers have shown that the use of forced-air warming does not increase either the risk of wound contamination in the operating room or bacterial contamination of operating theatres. In fact, research has shown that forced-air warming actually decreases the bacterial count at the surgical site. (Huang 2003)

- Because Bair Hugger blankets are single use, they cannot transmit infection from one patient to another. The same cannot be said for reusable products such as conductive warming blankets. The U.S. Centers for Disease Control and Prevention recommends disposable products for patients with known or suspected infections requiring contact precautions.

- We are unaware of any research that identifies forced-air warming units as the source of a surgical site infection. In contrast, normothermia maintenance has been identified as a key way to help combat SSI and forced-air warming has been specifically named in SSI reduction initiatives in the UK and elsewhere.

- The NICE guideline for "The management of inadvertent perioperative hypothermia in adults" recommends pre-operative and intra-operative use of forced-air warming. The NHS *Saving Lives* programme states: "Maintaining a body temperature above 36.0°C in the perioperative period has been shown to reduce infection rates." In the U.S., the SSI reduction initiative of the Institute for Healthcare Improvement's *5 Million Lives* campaign advises thousands of participating U.S. facilities to "Use warmed forced-air blankets preoperatively, during surgery and in PACU."

- We recommend routine cleaning and maintenance of our warming units. Most forced-air warming blankets are not sterile, nor do they enter the sterile field.

- Beyond generating baseless arguments about decontamination, the ABD letter contains information that is both misleading and false. Below are two of the more deceptive statements:
  - *Allegation:* "*Infection Control and Hospital Epidemiology* reported an outbreak of multi-drug resistant *Acinetobacter* that was traced directly to the inside of a Bair Hugger machine."
    FACT: A review of the paper (Bernards 2004) shows that the source of the infection was never determined, and certainly was not directly traced to a Bair Hugger machine.
  - *Allegation:* "A Department of Public Health in the U.S. described Bair Hugger machines as 'reservoirs of infection.'"
    FACT: Suzanne Beavers, MD, the author of the newsletter article to which ABD refers, has fully refuted this statement. (See attached letter).

- Forced-air warming has been used to safely and effectively maintain patient normothermia since it was introduced 20 years ago and more than 100 million patients have experienced its benefits.

- Forced-air warming has been studied extensively, with over 100 published studies documenting the important role of forced-air warming in maintaining normothermia.

AUGUSTINE
BIOMEDICAL+ DESIGN

Mr. Gary Maharaj
CEO
Arizant Healthcare Inc.
10393 West 70th St.
Eden Prairie, MN 55344

April 2, 2010

Re: Arizant's obligation to disclose and report

Dear Gary,

Two-and-a-half years ago we disclosed to Arizant and to the world that the internal airflow paths of Bair Hugger blowers are contaminated with bacteria and cannot be decontaminated (see BlowingAirIsRisky.com). The presence of bacteria in the airflow path and in the outlet air of the Bair Hugger blower presents an obvious risk of contamination in the operating room. Since then we have completed three more studies (one published and two pending publication), that all show the contamination issue to be much worse than we originally reported. The additional facts that; 1.) the airflow path cannot be cleaned (much less "decontaminated") and 2.) that decontamination instructions have not been supplied by the manufacturer, directly violate the Medical Devices Directive (MDD) for CE certification, FDA and Health Canada regulations.

Six months ago, we disclosed to Arizant and to the world that the waste heat from Bair Hugger warming disrupts the protection of laminar flow ventilation in the operating room. In subsequent research pending publication, we have shown that, in the presence of laminar flow and a single "surgeon" standing by the operating table, waste heat from a Bair Hugger lower body blanket can mobilize contaminates from the floor and convey them to the surgical site in such high concentrations that 50% of the air at the surgical site is from the floor and 50% is from the laminar flow ventilation.

I have enclosed a partial list of current research regarding the contamination problems from FAW. Doing this research has not been easy since whenever Arizant finds a study that is about to start, they have swooped into that hospital and exchanged all of the old blowers for new ones, for free! If my equipment was found to have a major problem, especially if it involved patient safety, I would want to characterize and fix that problem ASAP – before the plaintiff's attorneys got a hold of it. Just the opposite seems to be occurring here. Either Arizant is actively trying to prevent research that could help document and define the problem or you have an unannounced free upgrade program and an amazing timing coincidence with our research projects.

At this point, there is no question that FAW creates an increased risk of wound <u>contamination</u> during surgery. As such, you have a reporting obligation to both the regulatory authorities and to your customers. Instead, Arizant has taken the erroneous position that until <u>infections</u> are proven to have been caused by FAW, there is no problem that needs reporting. This is a similar logic to Guidant failing to fix their faulty

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defibrillator leads (which they knew were faulty), because no one had been proven to have been killed by the failures. As you know, Guidant was not only forced into a mandatory recall that nearly destroyed the company, but is now under criminal indictment.

Inexplicably to me, Arizant has chosen to publicly deny, mislead and even lie to customers about the problems. You are obfuscating the contamination issue in the rhetoric of "no proven infections" and quoting from woefully inadequate infection studies, when the issue (at this date, at least) is contamination and not infection. You are treating the contamination issue as though it were an inconvenient marketing attack rather than a patient risk that requires reporting. This is a regulatory issue, not simply a marketing inconvenience.

Even more inexplicably, you have recently made the situation even worse. In the face of demands by researchers that you add a hose-end filter because of blower contamination, you have recently reduced the effectiveness of your already-inadequate inlet filtration. While continuing to claim "high-efficiency .2 micron" filtration to the US FDA, the UK National Health Service and your customers, you have actually reduced the efficiency of your inlet filter to only 61.3%. Since "High Efficiency" aka "HEPA" is defined as 99.97% efficient, your current filter is nowhere near "high efficiency" and in fact is not too much better than a window screen. At the very least, this reduction in safety required a full ISO 14971 Risk Analysis and submission of a new 510(k). I can only assume that this change was made to improve the bottom-line for your financial owners, or to provide the air-flow needed for your expensive new underbody blankets. In any case, making the change secretly was wrong. I urge you to report and fix the problem.

Since the internal airflow path of a Bair Hugger blower cannot be cleaned, much less decontaminated, it is arguable that your problem cannot be fixed – the regulations clearly call for decontamination of reusable devices. However, it is possible that the regulators would regard adding a hose-end filter as a reasonable substitute for decontamination. I suggest that this positive outcome is most likely if you voluntarily bring the problem and the solution to the regulators yourselves.

As I am sure you know, we have patents pending on every practical method of adding a hose-end filter to a convective warming system (see enclosed). Please let me know if you have an interest in acquiring them. Personally, I believe that the short-term survival of Bair Hugger, is dependent on adding a hose-end filter. You may, of course, choose to ignore our intellectual property and create your own hose-end filter. This would lead to litigation when our patents issue.

No matter what you decide in this regard, when our currently submitted research studies are accepted for publication (which we anticipate by mid-May), we will take this evidence of contamination to the regulators in the US and Europe (FDA, Health Canada and 27 Competent Authorities in the EU countries). As we see it, there are 29 separate opportunities for us to educate a regulatory authority about the contamination risks created by Bair Hugger.

Consider that it only takes one airborne bacterium to infect an orthopedic implant, and we can show that in the presence of Bair Hugger warming, 50% of the air above the surgical site came from the contaminated blower and floor air. Also consider that it only takes one of the 29 regulators, who comprehends the seriousness of this risk and presumably the rest will follow that lead. If necessary, however, we will support even more research—including DNA matching of the bacterium cultured from a wound infection against the bacteria found inside the Bair Hugger blower used on that infected patient.

Unless I am missing something, full and immediate reporting, restoring inlet filter efficiency to HEPA standards and adding a HEPA hose-end filter, is Bair Hugger's only chance to survive a mandatory recall. Of course, we cannot assure you that the regulators will agree - the regulations do specify "decontamination" with no mention of filtration as an acceptable alternative. However, the chances of the regulators agreeing seem to be much higher if you preemptively bring your own problem to them with a solution in hand.

I have no doubt that HotDog conductive fabric warming will ultimately replace FAW. The question for you to answer is the following; is Bair Hugger going to be replaced quickly and catastrophically by a mandatory recall, or do you survive a voluntary recall and live to fight another day? Obviously, avoiding a mandatory recall is critical to maintaining shareholder value.

I am available to discuss this offer in more detail by phone or in person.

Regards,

Scott

Scott Augustine MD
CEO

AUGUSTINE
BIOMEDICAL+ DESIGN

Mr. David Westlin
Chief Regulatory Officer
Arizant Healthcare Inc.
10393 West 70th St.
Eden Prairie, MN 55344

April 2, 2010

Re: Arizant's obligation to disclose and report

Dear David,

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Six months ago, we disclosed to Arizant and to the world that the waste heat from Bair Hugger warming disrupts the protection of laminar flow ventilation in the operating room. In subsequent research pending publication, we have shown that, in the presence of laminar flow and a single "surgeon" standing by the operating table, waste heat from a Bair Hugger lower body blanket can mobilize contaminates from the floor and convey them to the surgical site in such high concentrations that 50% of the air at the surgical site is from the floor and 50% is from the laminar flow ventilation.

I have enclosed a partial list of current research regarding the contamination problems from FAW. Doing this research has not been easy since whenever Arizant finds a study that is about to start, they have swooped into that hospital and exchanged all of the old blowers for new ones, for free! If my equipment was found to have a major problem, especially if it involved patient safety, I would want to characterize and fix that problem ASAP – before the plaintiff's attorneys got a hold of it. Just the opposite seems to be occurring here. Either Arizant is actively trying to prevent research that could help document and define the problem or you have an unannounced free upgrade program and an amazing timing coincidence with our research projects.

At this point, there is no question that FAW creates an increased risk of wound <u>contamination</u> during surgery. As such, you have a reporting obligation to both the regulatory authorities and to your customers. Instead, Arizant has taken the erroneous position that until <u>infections</u> are proven to have been caused by FAW, there is no problem that needs reporting. This is a similar logic to Guidant failing to fix their faulty

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defibrillator leads (which they knew were faulty), because no one had been proven to have been killed by the failures. As you know, Guidant was not only forced into a mandatory recall that nearly destroyed the company, but is now under criminal indictment.

Inexplicably to me, Arizant has chosen to publicly deny, mislead and even lie to customers about the problems. You are obfuscating the contamination issue in the rhetoric of "no proven infections" and quoting from woefully inadequate infection studies, when the issue (at this date, at least) is contamination and not infection. You are treating the contamination issue as though it were an inconvenient marketing attack rather than a patient risk that requires reporting. This is a regulatory issue, not simply a marketing inconvenience.

Even more inexplicably, you have recently made the situation even worse. In the face of demands by researchers that you add a hose-end filter because of blower contamination, you have recently reduced the effectiveness of your already-inadequate inlet filtration. While continuing to claim "high-efficiency .2 micron" filtration to the US FDA, the UK National Health Service and your customers, you have actually reduced the efficiency of your inlet filter to only 61.3%. Since "High Efficiency" aka "HEPA" is defined as 99.97% efficient, your current filter is nowhere near "high efficiency" and in fact is not too much better than a window screen. At the very least, this reduction in safety required a full ISO 14971 Risk Analysis and submission of a new 510(k). I can only assume that this change was made to improve the bottom-line for your financial owners, or to provide the air-flow needed for your expensive new underbody blankets. In any case, making the change secretly was wrong. I urge you to report and fix the problem.

Since the internal airflow path of a Bair Hugger blower cannot be cleaned, much less decontaminated, it is arguable that your problem cannot be fixed – the regulations clearly call for decontamination of reusable devices. However, it is possible that the regulators would regard adding a hose-end filter as a reasonable substitute for decontamination. I suggest that this positive outcome is most likely if you voluntarily bring the problem and the solution to the regulators yourselves.

As I am sure you know, we have patents pending on every practical method of adding a hose-end filter to a convective warming system (see enclosed). Please let me know if you have an interest in acquiring them. Personally, I believe that the short-term survival of Bair Hugger, is dependent on adding a hose-end filter. You may, of course, choose to ignore our intellectual property and create your own hose-end filter. This would lead to litigation when our patents issue.

No matter what you decide in this regard, when our currently submitted research studies are accepted for publication (which we anticipate by mid-May), we will take this evidence of contamination to the regulators in the US and Europe (FDA, Health Canada and 27 Competent Authorities in the EU countries). As we see it, there are 29 separate opportunities for us to educate a regulatory authority about the contamination risks created by Bair Hugger.

Consider that it only takes one airborne bacterium to infect an orthopedic implant, and we can show that in the presence of Bair Hugger warming, 50% of the air above the surgical site came from the contaminated blower and floor air. Also consider that it only takes one of the 29 regulators, who comprehends the seriousness of this risk and presumably the rest will follow that lead. If necessary, however, we will support even more research—including DNA matching of the bacterium cultured from a wound infection against the bacteria found inside the Bair Hugger blower used on that infected patient.

Unless I am missing something, full and immediate reporting, restoring inlet filter efficiency to HEPA standards and adding a HEPA hose-end filter, is Bair Hugger's only chance to survive a mandatory recall. Of course, we cannot assure you that the regulators will agree - the regulations do specify "decontamination" with no mention of filtration as an acceptable alternative. However, the chances of the regulators agreeing seem to be much higher if you preemptively bring your own problem to them with a solution in hand.

I have no doubt that HotDog conductive fabric warming will ultimately replace FAW. The question for you to answer is the following; is Bair Hugger going to be replaced quickly and catastrophically by a mandatory recall, or do you survive a voluntary recall and live to fight another day? Obviously, avoiding a mandatory recall is critical to maintaining shareholder value.

I am available to discuss this offer in more detail by phone or in person.

Regards,

Scott

Scott Augustine MD
CEO

Clinical Research Summary and Update --- 3/2010

Scott Augustine MD

Forced Air Warming: Research Assessing the Risk of Blower Contamination, Airborne Contamination Emissions and Operating Room Ventilation Disruption

Published References:

1. Avidan MS, Jones N, Ing R, Khoosal M, Lundgren C, Morrell DF: Convection warmers--not just hot air. Anaesthesia. 1997; 52(11):1073-6.

Key findings: 10 FAW warmers were tested (9 Bair Hugger and 1 Warm Touch). Air blown from the hoses produced growth of pathogenic organisms from 4/10 blowers. 3/3 of these had positive cultures for the same organism in their hoses. "We conclude that these warming devices are a potential source of nosocomial infection." "A microbial filter fitted to the nozzle of the hose could be incorporated into the design of the warmer to reduce the risk of contamination."

2. Baker N, King D, Smith EG: Infection control hazards of intraoperative forced air warming. J Hosp Infect. 2002; 51(2):153-4.

Key findings: Swabs from the exterior and interior of the blower all resulted in "heavy growth of bacteria." Air blowing from the end of the hose grew colonies of coagulase-negative *staphylococci, Bacillus spp., and Micrococcus spp*. "At present there seems insufficient evidence to justify the routine use of forced air warming units as a intraoperative measure during ultraclean orthopaedic surgery."

3. Bernards AT, Harinck HIJ, Dijkshoorn L, van der Reijden TJK, van den Broek PJ: Persistent Acinetobacter baumannii? Look inside your medical equipment. Infect Control Hosp Epidemiol. 2004; 25(11):1002-4.

Key findings: "Two outbreaks of multidrug-resistant *Acinetobacter baumannii* occurred in our hospital…During the subsequent environmental investigation of the first outbreak, the outbreak strain was isolated from medical equipment (ie, from dust in the interior of a mechanical ventilator and from filters inside the Bair Hugger)…After this dust was removed, no further cases were observed."

4. Leaper D, Albrecht M, Gauthier R: Forced-air warming: a source of airborne contamination in the operating room? Orthopedic Rev. 2009; 3;1(2):e28.

Key findings: 25 Bair Hugger blowers sampled in their operating room environment. Pathogenic bacteria were cultured from the internal air-flow paths of 94% of the blowers. 32% of the blowers tested were emitting internally generated airborne contamination in the size range of bacteria. 24% of the blowers tested were emitting "significant levels of internally generated airborne contamination. "…findings in this study and those of others suggest that bacteria colonize the internal air path surfaces

of the majority of FAW blowers. The findings also suggest that a significant percentage of FAW blowers are emitting particulates, which were shown to originate inside the blowers." "EU Medical Device Directives require that reusable medical equipment should allow decontamination…instructions from FAW manufacturers do not provide a method of decontaminating the inside of the hose or blower…other authors have suggested the implementation of a distal hose end filter…Based upon the results of this study, FAW manufacturers should consider re-designing FAW blowers to insure compliance with mandates for internal decontamination and provide certifiable 'true HEPA' filtration… Clinicians should be aware that FAW blowers emit more than just hot air…"

5. Gjolaj MP, Ahlbrand S, Yamount IM, Armstrong D, Utne JG: Don't Forget to Change the Bair Hugger Filter. Proceedings of the 2009 Annual Meeting of the American Society of Anesthesiologists, A1168.

Key findings: The internal air-flow paths cultured positive growth in 12 of 29 Bair Hugger blowers. "As an added safety feature, it has been recommended that an additional microbial filter be fitted to the distal end of the BH hose."

6. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR: Guideline for Prevention of Surgical Site Infection, 1999. Centers for Disease Control and Prevention (CDC) Hospital Infection Control Practices Advisory Committee. Am J Infect Control. 1999; 27(2):97-132; quiz 133-134; discussion 96.

Key finding: The major source of airborne contaminants in the operating room air is the shed skin cells resulting form movement of the surgical staff, which carry microbes.

7. Lidwell OM. Air, antibiotics and sepsis in replacement joints: J Hosp Infect. 1988; 11 Suppl C:18-40.

Key finding: Over 95% of surgical site contamination during orthopedic surgery in standard operating rooms is airborne.

8. Whyte W. The role of clothing and drapes in the operating room: J Hosp Infect. 1988; 11 Suppl C:2-17.

Key finding: Laminar flow systems reduce the bacteria counts in the surgical site by 98% versus conventional ventilation.

Research submitted for publication:

1. Albrecht M, Belani K, Litchy M, Gauthier R, Leaper D: Forced Air Warming Blowers - an Evaluation of Filtration Adequacy and Airborne Contamination Emissions in the Operating Room. Submitted for peer review and publication.

Key findings: 52 Bair Hugger blowers sampled in their operating room environments. Micro-organisms were cultured from the internal air-flow paths of 92.3% of the blowers including *Staphylococcus aureus* 13.5%, coagulase negative *Staphylococcus aureus* 3.9% and methcillin resistant *Staphylococcus aureus* (MRSA) 1.9%.

58% of the Bair Hugger blowers tested were found to be internally generating and emitting significant levels of airborne contaminants >0.3 µm in size (germ size), up to 35,272 particles per ft^3 of air (80 million particles per hour). The tested blowers had a filtration efficiency of 93.8%, which is consistent with the known efficiency of the "older rev C" Bair Hugger filters. Five of the "newer rev D" filters were tested and showed a filtration efficiency of only 61.3%. This very low filtration efficiency is of particular note in light of Arizant's US FDA 510K filings, UK National Health Service (NHS) filings and representations by the sales force to customers worldwide have all claimed "HEPA" filtration efficiencies, which by definition means 99.97%.

2. XXXX X, Litchy M, Edwards-Jones V, Leaper D: An Evaluation Of Filtration Adequacy And Airborne Contamination Emissions From European Forced Air Warming Blowers. Submitted for peer review and publication.

Key findings: 23 Bair Hugger blowers were sampled in their operating room environments. Micro-organisms were cultured from the internal air-flow paths of 100% of the blowers including coagulase negative *Staphylococcus aureus* 74%, mold 26% and *Micrococci* 9%. The heaviest growth was reported on the internal surface of the elbows. 100% of the blowers were emitting internally generated particles >0.3 µm in size, up to 112,000 particles per ft^3 of air (300 million particles per hour). Emitted particle count was 40 times greater than the intake particle count for that blower, and virtually all of the emitted particles were internally generated. The mean filtration efficiency of the inlet filters was 63.8%, consistent with the "new rev D" Bair Hugger filter. The low efficiency filters may be responsible for the high level of internal contamination in the tested blowers.

3. XXXX X, XXXX X, Reed M, Harper M, Leaper D: Forced Air Warming Versus Resistive Polymer Blankets - An Evaluation of Laminar Flow Disruption. Submitted for peer review and publication.

Key findings: This study was designed to determine the effects of waste heat from either Bair Hugger forced air warming or HotDog conductive fabric warming on operating room laminar flow ventilation performance, in the presence of no surgical staff or a single "surgeon" standing in the laminar flow field. Tracer smoke particles were introduced under the operating table near the floor. Tracer particle concentrations were counted below the table and above the surgical site to determine a percentage of surgical site contamination. Under the conditions of "no waste heat load": HotDog "heat off", HotDog "heat on" high and Bair Hugger "heat off", less than 0.5% of the particles reached the surgical site. Therefore the high efficiency laminar flow ventilation system was very effective in protecting the surgical site from contamination in a "no waste heat load" condition and with no surgeon in the laminar flow. With the Bair Hugger "heat on" high producing a "waste heat load" but no surgeon, tracer particles at the surgical site increased to 3.1% ($P<0.05$), approximately a 10X increase. The addition of a surgeon standing next to the operating table increased the tracer penetration under "no waste heat load" conditions to: HotDog "heat off" 6.2%, HotDog "heat on" high 4.9% and Bair Hugger "heat off" 7.1%. Turning the Bair Hugger on "high" ("waste heat load" condition) in the

<u>presence of a surgeon dramatically increased the penetration of the laminar flow to 48.6%. In other words, despite the "protection" of laminar flow ventilation, half of the air immediately above the surgical site originated near the floor and was conveyed into the surgical site by the waste heat from the Bair Hugger</u>.

<u>Research projects in progress</u>: (Does not include pilot studies designed to preview the test methodology and outcomes.)

1. Working title: The effect of waste heat from forced air warming (FAW) on laminar flow and conventional operating theatre ventilation systems.
PI: XXXX XXXX MD
Location: XXXX University, UK
Hypothesis: The waste heat from FAW can be tracked by temperature mapping of the space around and over the operating table. The waste heat will be shown to warm the cooler ventilation air over the surgical site and the resulting temperatures will reflect mixing proportions.

2. Working title: An analysis of the disruption of laminar flow ventilation by heat from forced air warming (FAW) systems.
PI: XXXX XXXX PhD
Location: University of XXXX, Netherlands
Hypothesis: The disruptive effects of FAW waste heat on laminar flow ventilation can be shown using a sophisticated Computational Fluid Dynamics (CFD) model. The CFD model has been developed and validated for another study. The super computer results will then be validated against visible smoke in a laminar flow operating room.

3. Working title: Analysis of the air emitted from the hoses of Bair Hugger blowers.
PI: XXXX XXXX PhD
Location: XXXX University, UK
Hypothesis: In a UK hospital with an unusually high hospital acquired infection (HAI) and surgical site infection (SSI) rates, bacteria can be cultured from the air emitted from the hoses of the Bair Hugger blowers. Bacterial growth will be correlated with particle counts of the emitted air.

4. Working title: The effect of surgical staff on the penetration of laminar flow ventilation by forced air warming (FAW).
PI: XXXX XXXX MS
Location: University of XXXX, USA
Hypothesis: It has been shown that a single surgical staff person standing in the laminar flow significantly disrupts the laminar flow allowing waste heat from a Bair Hugger blower and contaminated air resident near the floor to rise into the surgical site. This study will asses if the addition of 1-3 more surgical staff around the table causes a higher percentage of waste air to reach the surgical site.

5. Working title: Identification of biofilms on the internal airflow paths of forced air blowers (FAW) and in the emitted air.

PI: XXXX XXXX PhD
Location: University of XXXX, UK
Hypothesis: Biofilms containing bacteria and bacterial DNA are present on the internal airflow paths of FAW blowers and in the emitted air. Microbial DNA can be identified using Polymerase Chain Reaction (PCR) techniques.

6. Working title: Tracer particle mapping of waste heat from forced air warming in a laminar flow operating theatre.
PI: XXXX XXXX PhD
Location: XXXX University, UK
Hypothesis: Tracer particles will correlate with visible smoke in mapping the disruption of laminar flow by the waste heat from Bair Hugger warming.

7. Working title: The effect of waste heat from forced air warming on laminar flow ventilation: calculated and observed.
PI: XXXX XXXX MS
Location: University of XXXX, USA
Hypothesis: The disruptive effect of FAW waste heat on laminar flow ventilation can be modeled and predicted with Computational Fluid Dynamics (CFD). This computer analysis will be compared to the measured temperatures mapped in a laminar flow laboratory.

8. Working title: Can pathogens from surgical site infections (SSI) be matched to microbial contaminates cultured from the internal airflow path of a forced air warming (FAW) blower?
PI: XXXX XXXX MD
Location: University of XXXX, UK
Hypothesis: Surgical site infections (SSI) are routinely cultured. When a deep SSI occurs in the presence of implanted foreign material, the internal airflow path of the FAW blower from the operating theatre where the surgery was performed will be extensively cultured. If an organism similar to the causative agent in the SSI is cultured from the blower, DNA testing will be performed on both organisms. When a match occurs, it can be concluded that the most probable cause of the infection was airborne contamination from the FAW blower.

9. Working title: Surgical site infection (SSI) and death rates in major orthopaedic prosthetic surgery: forced air warming vs conductive fabric warming.
PI: XXXX XXXX MD
Location: XXXX University, UK
Hypothesis: The SSI and death rate following major joint replacement surgery (hip and knee) resulting from trauma in elderly patients is relatively high. FAW will cause and increased rate of both SSI and death rate in this patient group compared to conductive fabric warming.

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Bair Hugger® Bair Paws®

Facts About Forced-Air Warming

Safe, effective forced-air warming proven to reduce surgical site infections

As the leaders in forced-air warming, we want to address some inaccuracies about forced-air warming that makers of competing technologies are promoting. We urge you to review the facts, forced-air warming's proven track record of safety and efficacy, and your own experience in assessing the important role forced-air warming plays in patient care.

- Forced-air warming is the **gold standard** of care for managing peri-operative normothermia in operating rooms throughout the world.[1-6]
- During the past **20 years**, more than **100 million patients** worldwide have been warmed peri-operatively using Bair Hugger therapy forced-air warming. In that time, there has **never been a report of a surgical site infection** linked to Bair Hugger therapy use.
- Forced-air warming has been studied extensively – there are **more than 100 published papers** documenting its clinical benefits.
- Published research papers have shown that the use of forced-air warming **does not increase** either the risk of wound contamination in the operating room or bacterial contamination of operating rooms.[7,8] In fact, when tested during actual surgical conditions, research has shown that forced-air warming actually **decreases the bacterial count** at the surgical site.[5]
- **Normothermia is an important tool in the fight against surgical site infections (SSIs).**[9-11] Healthcare quality initiatives, including guidelines from the National Institute for Health and Clinical Excellence (NICE), the National Health Service (NHS) Saving Lives program, the 1,000 Lives Campaign in Wales and Scotland's Patient Safety Programme all note the importance of normothermia maintenance in SSI reduction. Several of these organisations specifically mention forced-air warming as a key means of maintaining normothermia.
- Because Bair Hugger blankets are **single use, they cannot transmit infection** from one patient to another. The U.S. Centers for Disease Control and Prevention recommends disposable products for patients with known or suspected infections requiring contact precautions.[14]
- Most forced-air warming blankets are **not designed to be sterile, nor do they enter the sterile field**. When used properly and as intended, the filtered air flowing from a warming unit is gently and evenly dispersed throughout the attached warming blanket, which is isolated from the surgical site by an adhesive strip on the blanket and surgical barrier drapes. And like many kinds of theatre equipment, forced-air warming units also are isolated from the sterile field with surgical drapes.
- Arizant Healthcare recommends **routine cleaning and maintenance** of our warming units. Specific instructions for cleaning the warming unit and regularly changing the filter through which air flows **have proven appropriate** throughout Bair Hugger therapy's 20-year history. The CDC has published extensive guidelines on the appropriate procedures for cleaning medical equipment and avoiding nosocomial infections. These guidelines do not recommend or even mention cleaning the interior of convective warming devices.
- When tested during actual surgical conditions, forced-air warming systems do not increase bacterial counts at the operating site, which has been shown in both laminar and standard airflow operating theatres.[5,15]
- Forced-air warming blankets are designed to produce local, short-range increases in airflow velocity. Flow visualisation techniques demonstrate that the airflow from Bair Hugger blankets has no significant effect on operating theatre airflow.[15,16]
- Bair Hugger warming units provide a second level of filtration. Operating theatre air is already filtered, and the Bair Hugger unit filters inlet air again with a high efficiency 0.2 micron filter. Air from the warming blanket is also isolated from the surgical site by barrier drapes and is forced down by the operating theatre air curtain.
- Bacterial shedding from operating room personnel, especially from foreheads, eyebrows, and ears is the most significant source of bacterial contamination.[17]
- The motion of air in the theatre is regulated and tested. Air velocity typically 25-35 ft/min[16], while air exchange is typically 20-25 times per hour.[16] Laminar flow is believed to reduce turbulence using air moving in an orderly way as a single column. Air velocity within the operating theatre is many times stronger than that of the forced-air warming blanket.

We know forced-air warming. We created the category. It's at the core of who we are and what we do. Every day, we devote ourselves to working with healthcare providers across the globe to bring patients the benefits of normothermia.

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Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Conventional (non-laminar, positive pressure) Operating Room Ventilation Disruption

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Key words: surgical site infection, forced air warming, laminar air flow, operating room environmental contamination, operating room ventilation.

Abstract

Introduction: Conventional (non-laminar, positive pressure) operating room (OR) ventilation is designed to protect the surgical site from airborne pathogenic contaminants. Conventional ventilation performance is fragile in nature and can be compromised by flow obstructions (personnel) and thermals (heated air). The waste heat generated by patient warming systems used to prevent surgical hypothermia, represent a potential source of ventilation disruption. We compared the effects of two patient warming modalities classified as having "low waste heat load" (conductive fabric warming – "CFW") and "high waste heat load" (forced air warming – "FAW") on operating room ventilation performance.

Methods: In a ventilation laboratory with 0.3 m/s airflow simulating a conventional OR, a mannequin was draped for an abdominal incision. Smoke particulate was introduced at floor level under the operating table as a tracer. Ventilation performance was assessed by determining the ratio of tracer detected 15 cm above the surgical site to the tracer detected 50 cm above the floor. Each patient warming device (lower body blanket/coverlet) was tested with and without the presence of a surgeon standing next to the operating table.

Results: With a surgeon present, FAW on "high" heat resulted in a large increase in the percentage of tracer-laden air from under the operating table detected at the surgical site versus FAW ambient control (63.0% v 6.9%). In contrast, with a surgeon present, CFW on "high heat" resulted in no increase in the percentage of tracer-laden air detected at the surgical site versus CFW ambient control (4.9% v 6.1%).

Conclusion: The use of FAW was found to generate sufficient waste heat to disrupt conventional OR ventilation and mobilize tracer contaminated air from under the table upwards and into the surgical site. The surgeon's body was found to act as a flow-stabilizing boundary against which the heated air could rise. Detected particle counts showed that in the presence of a single surgeon, the waste heat from FAW on "high" could mobilize sufficient quantities of tracer-laden floor air, so that more than half of the air directly above the surgical site consisted of potentially pathogenic floor air.

In contrast, conductive fabric warming did not generate sufficient waste heat to affect ventilation performance.

Introduction

Operating room (OR) ventilation plays a critical role in preventing surgical site infection (SSI) by protecting the operative site from microbial-laden dust, lint, skin squames, and respiratory droplets resident in OR air.[1-7] OR ventilation systems are classified as either conventional or laminar based upon their design: conventional systems supply a non-laminar (turbulent) airflow filtered to an efficiency of ≥90%; laminar systems direct a uniform velocity airflow (0.3 to 0.5 m/s) over the surgical site filtered to an efficiency of ≥99.97% to sweep away contaminants.[8,9] Laminar ventilation offers added protection from airborne contaminants and is typically utilized for contamination-sensitive operations, such as the implantation of prosthetics.[10] Recent research has challenged the use of forced air warming (FAW) due to the risks of FAW-generated contaminants in the vented waste airflow.[11-15] However, these studies focused on quantifying contaminants in the air effluent from FAW blowers and did not consider a second, but equally important source of SSI risk: the disruption of OR ventilation due to vented waste heat from FAW devices.

OR ventilation performance is fragile in nature and highly sensitive to flow obstructions (surgical lights, people, etc…) and movements of the surgical staff, both of which create regions of turbulence in the downward airflow that draw contaminants into the surgical site.[16,17] Adequate downward flow velocity has been identified as the critical factor for lessening the impacts of these factors on ventilation performance.[18] However, even moderately heated air from surgical equipment and lamps has been shown to have sufficient buoyancy to greatly reduce the downward velocity of the ventilation flow in a localized region.[18]

The vented waste heat emitted from FAW blowers is a far greater source of thermal energy than all commonly used OR equipment. The heated airflow from FAW blowers is released at 43°C, which is often 20°C above ambient OR conditions and can contribute upwards of 800 watts of vented waste heat in close proximity to the surgical site.[19,20] The release of such thermal energy has the potential to generate temperature gradients that

impede the performance of the OR ventilation system. Further, the release of FAW-vented waste heat is often directed towards the floor into resident air that is potentially contaminated with shed skin cells and bacteria. Intuitively, it seems logical to vent the waste air and heat from FAW toward the floor, away from the surgical site. However, since the vented waste heat is buoyant, it may be possible for it to mobilize contaminated air near the floor towards the surgical site, against the downward ventilation flow. Supporting evidence for this phenomenon can be seen in a recent research video that captures the effects of forced air warming waste heat-generated air currents on OR ventilation performance.[21]

Surgical procedures done in conventional (non-laminar) flow ORs are generally less susceptible to airborne contamination than those typically performed in laminar flow ORs. None-the-less, there is a presumption of air cleanliness in every OR. Additionally, air-free alternatives, such as conductive fabric warming (CFW), have been developed that are comparably effective to FAW for the prevention of surgical hypothermia.[22-28] With the availability of such alternatives, there is a need to critically assess the impact of FAW versus air-free alternatives on OR ventilation performance. Given that the majority of ORs employ some form of conventional ventilation, we chose to study the effects of FAW versus CFW on ventilation performance in a ventilation laboratory modified to approximate a conventional-flow ventilation OR.

This study was specifically designed to:

(i) Compare the effects of waste heat from the use of either FAW or CFW on conventional OR ventilation performance in:

1) an OR environment having no surgical staff; and

2) an OR environment having a single surgeon standing by the surgical table.

(ii) Determine whether sufficient waste heat is generated to mobilize air resident near the floor, towards the surgical site by the use of either FAW or CFW.

Methods

OR Ventilation Laboratory Setup

A OR ventilation laboratory was created for this experiment because most hospital ORs will not allow smoke or the open flame necessary to produce tracer smoke. The location of the ventilation air diffusers was chosen to represent an average conventional ventilation OR. The ceiling directly over the surgical table generally does not have diffusers because it serves as the mounting location for the pedestal of the surgical light. Since there is no standard conventional ventilation diffuser design or standard diffuser location, we elected to arrange the ventilation diffusers in a complete ring around the periphery of the non-flow central area directly above the surgical table **(Fig 1)**.

It is well known that conventional ventilation diffusers create jetting and turbulent airflow.[9] The jetting and turbulence is unpredictable and difficult to reproduce, especially when interacting with the airflow from adjacent diffusers. Turbulence and jetting can cause eddy currents and counter currents that can accentuate the adverse effects of rising waste heat. We elected to minimize the turbulence and jetting in order to isolate the effects of the waste heat as much a possible. Therefore, we passed the ventilation air through a layer of filtration media (Technostat, Hollingsworth and Vose, East Walpole, MA), as it exited the diffusers.

The conventional flow ventilation laboratory **(Fig 2)** employed a HVAC ventilation blower that provided a pressurized airflow to a ceiling plenum having a cross sectional area of 2.4 by 2.4 meters. A 50 cm x 50 cm area in the center of the plenum was blocked from any airflow to simulate the mounting location for the surgical light directly over the surgical table. The surface of the plenum was covered with filtration media, creating a downward non-jetting, minimally-turbulent (but also non-laminar) flow surrounding the operating table having an average velocity of 0.3 m/s, as measured 50 cm below the plenum. The plenum created a ring-like airflow surrounding the operating table that diffused inward and outward as it descended, thus, converging directly over the table despite having no airflow from the ceiling in this location. The air exited the laboratory

through a series of 8 vent grates (20 by 40 cm) located 30 cm from the floor, with 2 vent grates in each wall. When in operation, the laboratory created a positive pressure of 0.15 cm H_2O inside the room having approximately 45 air changes per hour.

The absence of jetting and the convergence of the airflows over the surgical table were visually verified by streaming smoke. The smoke stream was generated with a theatrical smoke generator (Rocket PS23, Pea Soup Ltd, United Kingdom) and pumped by an aquarium bubbler pump through 5 m of 1 cm plastic tubing. The distal end of the tubing was manually held in various locations near the diffuser on the ceiling and the streaming of the smoke was observed.

Under the center of the plenum, a mannequin was laid in a supine position on the operating table and draped in accordance with standard operating procedures for an abdominal incision (**Fig 3**). Draping consisted of laying a full body surgical drape with no surgical site opening across the mannequin, with the sides and foot end of the drape hanging downwards and terminating 50 cm off of the floor. At the head of the table, the drape was tented to create an ether screen for anesthesia access. The experimental warming treatment was introduced under the drape and applied to the mannequin's legs and was either: 1) a lower body FAW coverlet (Bair Hugger Model 525, Arizant Healthcare, Eden Prairie, MN); or 2) a lower body CFW blanket (Hot Dog Model B103, Augustine Temperature Management LLC, Eden Prairie, MN). The CFW blanket turned "off" served as the control. An aerosolized smoke tracer was created outside the laboratory by burning "punk sticks" and the tracer smoke was delivered to the space under the operating table by means of a blower and hose delivering 0.028 m^3 per minute of airflow. The hose was sufficiently long to ensure that the particulate tracer had cooled and thermally equilibrated with the environment before introduction.

The CFW treatment was powered by a standard controller (Model WC02, Augustine Temperature Management). The FAW coverlet was powered by a FAW blower (Model 750, Arizant Healthcare) modified to have an in-line hose filter to insure that none of the particles detected at the surgical site originated within the blower. The in-line hose filter

was constructed of an electrostatic filtration media (Technostat, Hollingsworth & Vose) having a cross-sectional area of approximately 625 cm^2, which did not materially affect the airflow delivered to the FAW coverlet. The temperature of the air exiting the Model 750 FAW blower is controlled by a distal hose-end temperature sensor, downstream of the inline hose filter. Therefore, the in-line filter did not affect the temperature of the airflow delivered to the FAW coverlet.

Study Design

The experiment involved a non-replicated full factorial design with repeated measures (**Fig 4**) assessing changes in tracer particle concentration above the surgical site due to the effect of three 2-level factors defined as: 1) surgeon present or absent, with present defined as a gowned person standing next to the surgical site performing repeated hand movements over the mannequin's abdomen, but not touching anything; 2) patient warming modality, having the levels of FAW and CFW; and, 3) controller heat setting, having the levels of heater "off" (called "ambient" for FAW and "control" for CFW) and heater "on" high heat (43°C) for each therapy.

At the beginning of each day, ventilation uniformity and tracer particle concentrations under the operating table were recorded. FAW blower distal airflow particle concentrations were measured during day 3 of testing. For each treatment combination, tracer particle concentrations above the operating site were recorded via particle counting as described above.

Sampling Procedures

Measurements were made in the laminar flow laboratory over the course of 3 days to quantify:

(i) Ventilation flow uniformity, which was recorded using a hot wire anemometer (Model HHF42, Omega Engineering, Stamford, CT) that reported both temperature and air flow. Measurements of airflow and temperature were taken 50 cm below the ventilation air delivery plenum at four corners (30 cm diagonally inward from the corners of the ventilation plenum structure).

(ii) Tracer particle concentrations, which were measured: 1) "under the operating table" - defined as 50 cm off the floor under the operating table and between the lower edges of the surgical drape, which is the boundary zone between the warm waste FAW air and the air resident near the floor; 2) "above the surgical site" - defined as 15 cm above the abdomen of the draped mannequin; and 3) "within the FAW blower distal airflow" - defined as the core of the airflow 2 cm past the distal hose exit. Particle concentrations were recorded using a laser particle counter (Handilaz Mini, Particle Measuring Systems, Boulder, CO). For each measurement, particle counts of five 0.028 m^3 air samples were taken.

Assessments

Tracer penetration of the surgical site was calculated as the ratio of average particle concentration 15 cm above the surgical site to average particle concentration 50 cm off the floor under the operating table for each experiment. A pooled under-table average across all experiments was selected as the denominator because the under-table tracer concentrations were found to be relatively stable and consistent.

Tracer penetration of the surgical site indicates the degree to which tracer-laden under-table air was being mobilized upwards into the surgical site against the downward airflow currents. Values represent the percent mixture of the air in the region above the surgical site originating from near the floor under the operating table.

Statistical Analysis

Given that this was an observational study (non-randomized), we chose to report only mean values for each treatment combination and the corresponding standard error of the mean. Reported standard error of the mean values capture intra-experiment variability; the non-replicated nature of the design prevents the estimation of inter-experiment variability.

Results

Experimental runs were performed representing the 8 treatment combinations identified by the experimental design (**Fig 4**). Temperature and air velocity measurements

confirmed a stable and uniform conventional flow environment, which had a temperature ranging from 21.0 to 21.5°C and an air velocity of 0.3 m/s over the course of experiments. A pooled under-table tracer particle concentration average of 66.4 particles ≥0.3 μm/cm^3 was used as the denominator in all calculations. The variation in under-table tracer particle concentration was small compared to the magnitude of observed treatment effects. **(Table 1)**

Measurements of airflow exiting the FAW blower showed tracer particle concentrations to be 0.4% of those in under-table air. This small percentage indicates that the added in-line hose filter was very effective at removing tracer particulate from the airflow supplied to the FAW coverlet. Thus, any tracer particle detected above the table at the surgical site did not come from the FAW blower.

Tracer Penetration of the Surgical Site

For experiments performed without a surgeon, there appeared to be no significant difference in tracer penetration of the surgical site between experimental treatments having "minimal or no waste heat": CFW "heat off" (control) reported 0.4% penetration; CFW "heat on" reported 0.3% penetration; and FAW "ambient" reported 0.3% penetration (**Fig 5**). Thus, these treatment combinations had no effect on conventional ventilation performance. The use of FAW with the "heat on" added a "waste heat" load to the system, and under the same conditions (no surgeon) was found to moderately elevate tracer penetration of the surgical site to 1.5 %.

The addition of a surgeon, simply standing next to the operating table, led to a moderate elevation in tracer penetration of the surgical site for experimental treatments having "minimal or no waste heat": CFW "heat off" (control) - 6.1%, CFW "heat on"- 4.9%, and FAW "ambient"- 6.9%. Given the overlap in dispersion indices, these experimental treatments having "minimal or no waste heat" appeared to have a similar effect on ventilation performance. In contrast, experimental treatments having a "waste heat" load exhibited a large effect on ventilation performance. The use of FAW on "high heat" elevated tracer penetration of the surgical site to 63.0%. Compared to treatments having

"minimal or no waste heat", the use of FAW on "high heat" in the presence of a surgeon resulted in an approximately 10-fold increase in the quantity of tracer-laden air from under the table reaching the surgical site.

Discussion

This is the first study to assess the impact of two different patient warming modalities, FAW and CFW, on conventional (non-laminar, positive pressure) ventilation performance in an OR environment. The results of this study suggest that the use of FAW can generate sufficient vented waste heat to disrupt the conventional ventilation airflow protecting the surgical site from airborne contaminants. Further, the adverse effects of FAW-vented waste heat were found to be exponentially magnified when a surgeon stands by the operating table. In contrast, the use of CFW was shown to have no effect on ventilation performance. The results also showed FAW waste heat vented near the floor, can mobilize contaminated air resident near the floor into the surgical site from under the surgical table.

We felt it was important to perform the experiment using a FAW lower body blanket to ensure that airflow exiting the coverlet was vented downwards and away from the surgical site. Thus, any tracer particles reaching the surgical site would be due to upward air currents originating from under the operating table. Further, tracer particles were cooled to room temperature before introduction under the operating table to assure that they did not contribute to the "waste heat" load. Particle counting demonstrated that the stability of the conventional ventilation environment in the vicinity of the surgical site was unaffected by the use of CFW in the heat "on" or "off" condition. The conventional ventilation was also unaffected by FAW in the heat "ambient" condition. For those conditions classified as having "minimal or no waste heat", the conventional ventilation system was effective for protecting the surgical site from under-table tracer particles.

In contrast, the use of FAW with heat "on" was found to greatly impact the stability of the conventional ventilation environment. Simply turning the FAW heat "on" resulted in roughly a 10-fold elevation in the number of tracer particles detected above the surgical

site when compared to treatments having "minimal or no waste heat." OR environments are normally maintained in the range of 20-25°C, meaning that the vented waste heat from FAW can be as much as 10-20°C in excess of the ambient environment. Such temperature differences impart a natural buoyancy to the vented FAW waste air that causes it to rise upwards towards the surgical site. In our study, the waste air and heat from FAW accumulated under the "tent" formed by the operating table and the lower edges of the surgical drape. The heated air then escaped from under the lower edges of the drape and appeared to rise along the sides of the operating table towards the surgical site.

The ability of the vented waste heat to rise against the downward ventilation flow was found to be highly dependent on whether a surgeon was present in the environment. The presence of a surgeon has two distinct effects on the stability of the ventilation flow. First, independent of patient warming, the surgeon's body physically disrupts the downward flow and creates a turbulent wake that extends outward in the profile of an expanding cone.[29] This "wake" effect is the most plausible explanation as to why tracer particle counts were found to be equally elevated for all "minimal or no waste heat" conditions when a surgeon was added to the environment. For FAW with heat "on", there is a second effect due to vented waste heat that must be considered: flow boundary stabilization.[29] The velocity of the downward ventilation airflow is greatly reduced in the vicinity of any rigid body (actually, zero at the surface), thus, the space between the surgeon's body and operating table experiences a significant reduction in downward airflow velocity. The reduced downward velocity of the airflow in this space causes it to be easily overcome by the buoyancy of the vented waste heat, which is able to rise through this space and into the surgical site. As evidence of this phenomenon, the combination of FAW vented waste heat and the presence of a surgeon resulted in a 63.0% tracer penetration of the surgical site. In other words, over half of the air immediately over the surgical site came from the air resident near the floor below the surgical table, even though the surgical site was protected by a properly functioning conventional ventilation system operating at 0.3 m/s.

The final objective of this experiment was to determine if the airflow reaching the surgical site from below the operating table was composed of: 1) the vented waste heat and air exiting the FAW coverlet; and/or 2) the resident air near the floor. In our experiment, the FAW airflow entering the coverlet was filtered by an in-line filter and verified to be tracer free. Therefore, the tracer content of the air detected at the surgical site had to have come from tracer-laden air resident near the floor, which was conveyed towards the surgical site by the particle-free FAW vented waste heat. We are not aware that it has ever been previously demonstrated how thermal sources, in a properly functioning conventional ventilation system, can mobilize significant quantities of air resident near the floor towards the surgical site.

Research assessing the effects of thermals, such as surgical lamp or surgical equipment waste heat, on ventilation performance has found these effects to be minor.[17] Given that the heat release from surgical lamps occurs in the ventilation field, it is not surprising to find that the heat is quickly diluted and, thus, of minimal importance. Further, lights and surgical equipment generate much less waste heat than FAW.[18] In contrast, FAW use generates a large quantity of vented waste heat that is often released in a sheltered area under the operating table where it cannot be diluted and swept away by the ventilation flow.

The detection of resident air from the floor at the surgical site also suggests the possibility that FAW use may contribute to microbial contaminant mobilization, particularly since air near the floor is often laden with shed skin cells and bacteria. Prior research assessing FAW use and SSI risk has primarily focused on assessing the design of FAW blowers in regards to preventing contamination emissions in the effluent airflow.[11-15] These studies have identified inadequate intake filtration performance as contributing to internal contamination build-up within FAW blowers and the consequent emission of contaminants in the effluent airflow. As a solution to the problem, these authors have generally suggested the addition of distal hose end HEPA filters for all FAW blowers. However, the results of this study show that even with a hose end filter, and thus contamination-free FAW waste air, the waste heat alone can mobilize

potentially contaminated floor air into the surgical site. As such, further research is recommended to characterize how the use of FAW affects the mobilization of resident floor contaminates and not just FAW-generated contaminants. Ideally, this research should be focused on understanding whether FAW waste heat mobilizes sufficient contaminants to elevate SSI risks.

A limitation of the present study is that it was performed in an OR ventilation laboratory having a single surgeon without the usual flow obstructions present, such as lights and surgical equipment. The inclusion of these factors is likely to magnify the disruptive effects of FAW waste heat and should be studied in a variety of conventional ORs under appropriate surgical conditions. Additionally, the relevance of such research may be greater for surgeries involving the implantation of foreign materials such as prosthetic joints, where the risks of SSI due to airborne contaminants increases exponentially.[30,31] Therefore, the effects of FAW waste heat on ventilation performance should be critically examined in laminar flow ventilation environments.

Conclusion

This study assessed the effects of two comparably effective patient warming systems, FAW and CFW, on conventional (non-laminar, positive pressure) OR ventilation performance. The results showed FAW to disrupt conventional ventilation performance. In contrast, CFW had no effect on ventilation performance. This study also demonstrates the ability of FAW "waste heat" to mobilize significant amounts of potentially contaminated air resident near the floor, upwards and into the surgical site. Until the SSI risks resulting from FAW ventilation disruption can be further evaluated, the use of air-free patient warming alternatives might be recommended for contamination sensitive procedures such as orthopedic prosthesis implants.

Table 1. Background characteristics of laboratory ventilation environment.

Under-Table Tracer Concentration, mean (stdev) [Particles ≥0.3 µm/cm^3]	
Day 1	66.1 (3.0)
Day 2	64.1 (1.3)
Day 3	69.0 (0.7)
Pooled Average	66.4 (2.8)
Forced Air Warming Blower Distal Airflow Tracer Concentration, mean (stdev) [Particles ≥0.3 µm/cm^3]	
Day 3	0.3 (0.1)
Laminar Flow Temperature Uniformity, mean (stdev) [°C]	
Day 1	21.0 (0.0*)
Day 2	20.5 (0.0*)
Day 3	20.5 (0.0*)
Laminar Flow Velocity Uniformity, mean (stdev) [m/s]	
Day 1	0.3 (0.0*)
Day 2	0.3 (0.0*)
Day 3	0.3 (0.0*)

* no variation existed at time of measure across air plenum; stdev, population standard deviation.

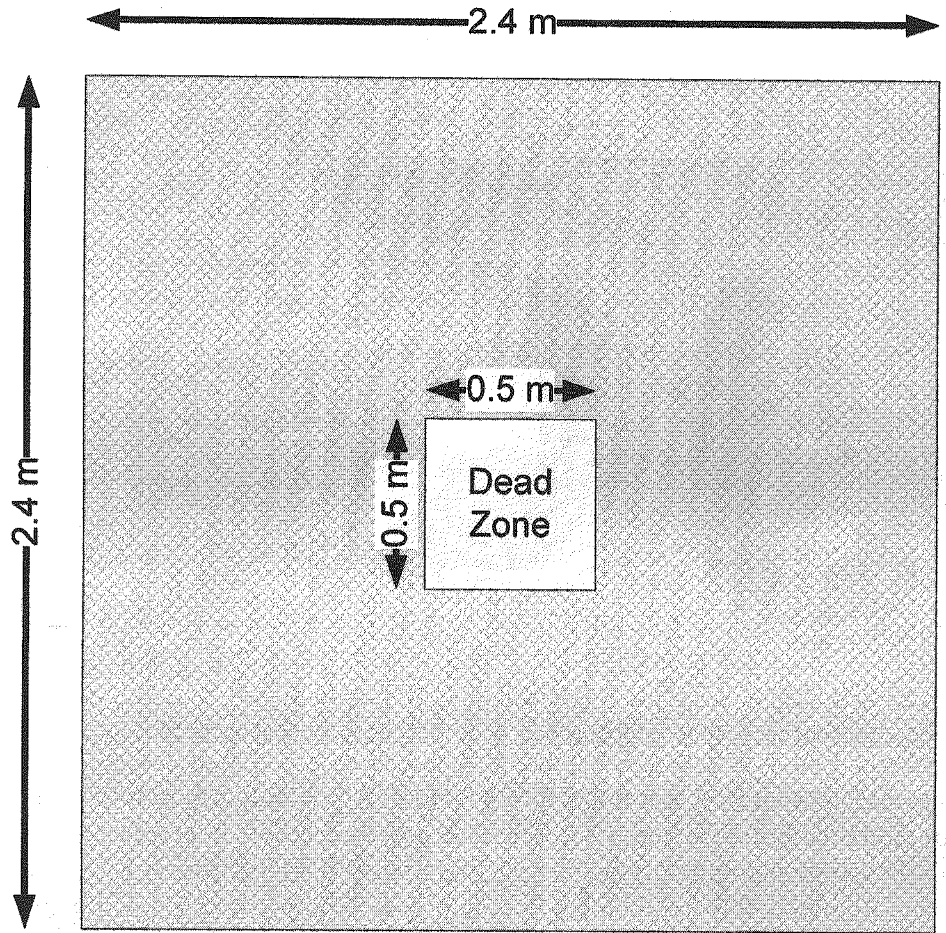

Figure 1: Ventilation laboratory ceiling diffuser design.

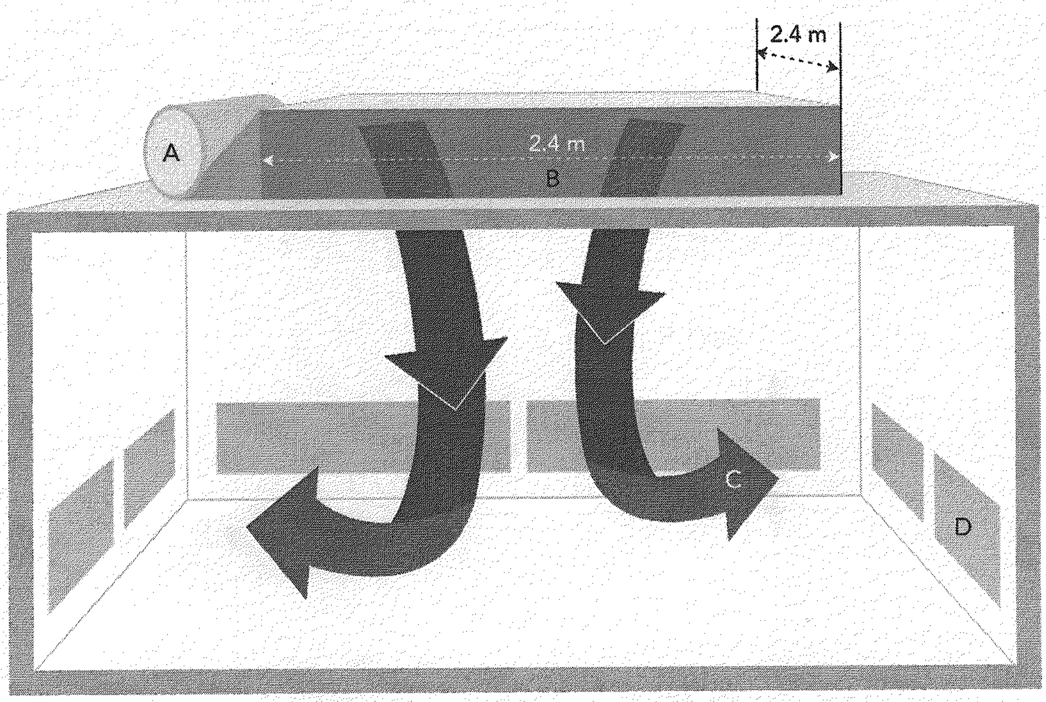

Figure 2: Conventional ventilation laboratory, having an HVAC ventilation blower (A) that pressurizes an air distribution plenum (B). The pressurized airflow enters the laboratory through the lower plenum surface and is filtered as it passes through a layer of filtration media. The filtered airflow (C) enters the laboratory in a downward fashion at an average velocity of 0.3 m/s. Waste airflow is exhausted through floor level return grates (D).

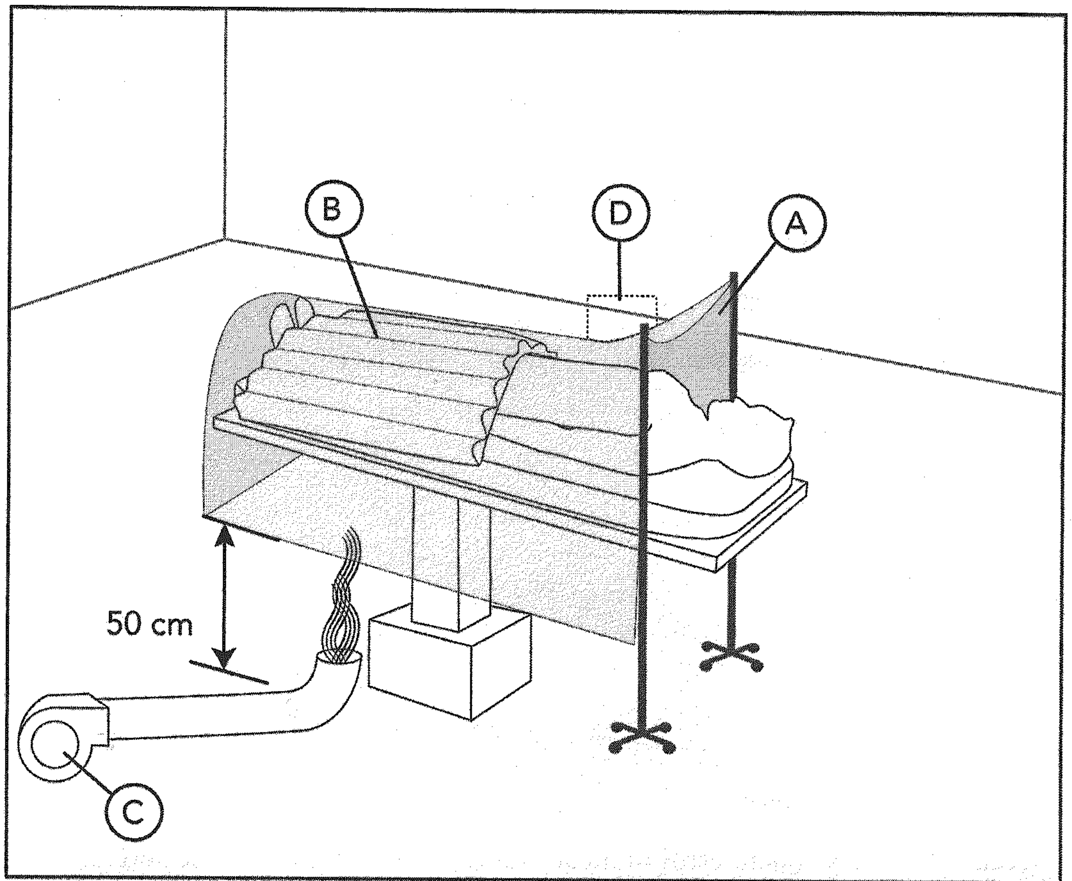

Figure 3: Experimental setup in center of ventilation laboratory with adult mannequin in the supine position, showing: (A) surgical draping; (B) experimental warming treatment (conductive fabric warming or forced air warming); (C) blower conveying tracer particle under the operating table; and (D) surgical site particle sampling location.

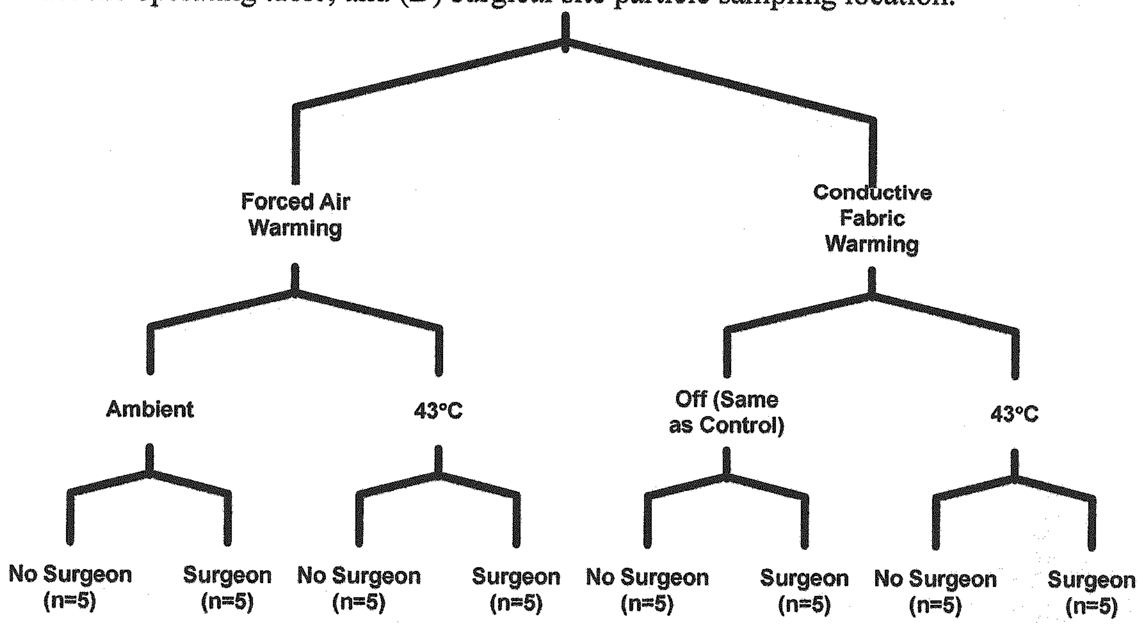

Figure 3: Un-replicated full factorial experimental design indicating the use of repeated measures for each experimental treatment.

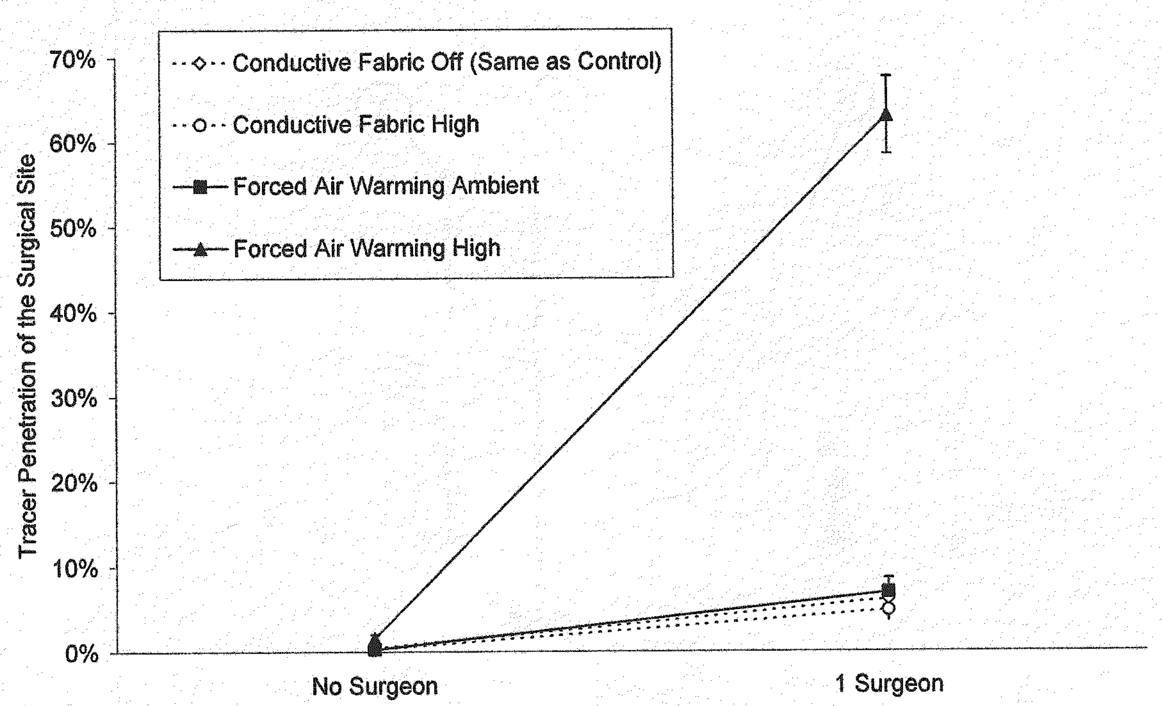

Figure 4: Mean values (± standard error of mean) for tracer penetration of the surgical site.

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Forced Air Warming versus Conductive Fabric Warming – An Evaluation of Laminar Operating Room Ventilation Disruption

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Key words: surgical site infection, forced air warming, laminar air flow, operating room environmental contamination, operating room ventilation

Abstract

Introduction: Operating room (OR) laminar ventilation is designed to protect the surgical site from airborne pathogenic contaminants. Laminar ventilation performance is fragile in nature and can be compromised by flow obstructions (personnel) and thermals (heated air). Patient warming systems, used to prevent surgical hypothermia, represent a potential source of ventilation disruption via the waste heat they generate. We compared the effects of two patient warming modalities classified as having "low waste heat load" (conductive fabric warming - "CFW") and "high waste heat load" (forced air warming – "FAW") on laminar ventilation performance.

Methods: Experiments were carried out in a ventilation laboratory simulating a laminar flow OR. A mannequin was draped for an abdominal incision and tracer smoke was introduced under the surgical drape. Neutral buoyancy detergent bubbles ("bubbles") were used to visualize airflows and particle counts of tracer smoke were performed 15 cm above the surgical site to quantitatively assess tracer mobilization into the surgical site. A randomized factorial design was employed to assess the effect of the following two-level factors on ventilation performance: lower body patient warming system (FAW or CFW); controller setting (ambient/off or 43°C); ventilation airflow (0.3 or 0.5 m/s); tracer location (floor or legs); and, surgical team (empty room or 2 surgeons).

Results: Vented waste heat from FAW use at 43°C created warm-air convection currents that mobilized tracer particulate upwards against the downward laminar flow and into the surgical site, as indicated by bubbles. With no surgical staff, the use of FAW at 43°C resulted in a ≈30-fold increase in particle counts at the surgical site versus controls. With a surgical staff present, these counts were elevated ≈90-fold versus controls. CFW use at 43°C produced minimal waste heat and had no effect on airflow currents or particle counts at the surgical site versus controls.

Conclusion: The use of FAW generated sufficient waste heat to form convection currents that disrupted laminar ventilation performance and mobilized tracer contaminated air into the surgical site from high pathogenic-risk locations near the floor and under the drape. Bubbles showed the sheltered space between the surgeon's body and operating table as the primary area these convection currents form. In contrast, CFW did not generate sufficient waste heat to affect ventilation performance.

Introduction

Operating room (OR) ventilation plays a critical role in preventing surgical site infection (SSI) by protecting the operative site from microbial-laden dust, lint, skin squames, and respiratory droplets resident in OR air.[1-7] OR ventilation systems are classified as either conventional or laminar based upon their design: conventional systems supply a turbulent airflow filtered to an efficiency of ≥90%;[8] laminar systems direct a uniform velocity airflow (0.3 to 0.5 m/s) over the surgical site filtered to an efficiency of ≥99.97% to sweep away contaminants.[9] Laminar ventilation offers added protection from airborne contaminants and is typically utilized for contamination sensitive operations, such as the implantation of prosthetics.[10] Recent research has challenged the use of forced air warming (FAW) in such laminar environments due to the risks of FAW generated contaminants reaching the surgical site via the vented waste airflow.[11-15] However, these studies focused on solely quantifying contaminants in the direct air effluent from FAW blowers and did not consider a second, but equally important source of SSI risk: the disruption of OR laminar airflow due to vented waste heat from FAW devices.

Laminar airflows are fragile in nature and highly sensitive to flow obstructions (overhead surgical lights, people, etc…) and movements of the surgical staff.[16,17] both of which create regions of turbulence in the uniform airflow that draw contaminants into the surgical site. Adequate laminar flow velocity has been identified as the critical factor for lessening the impacts of these factors on ventilation performance. However, even moderately heated air from surgical equipment and lamps has been shown to have sufficient buoyancy to greatly reduce the downward velocity of the laminar flow in a localized region.[18]

The vented waste heat emitted from FAW blowers is a far greater source of thermal energy in the laminar flow field than nearly all commonly used OR equipment. The heated airflow from FAW blowers is released at 43°C, which is often 20°C above ambient OR conditions, and can contribute upwards of 800 watts of vented waste heat in close proximity to the surgical site.[19,20] The release of such thermal energy has the potential to generate temperature gradients that impede the performance of the laminar

flow ventilation system. Further, the release of FAW vented waste heat is often directed towards the floor into resident air that is potentially contaminated with shed skin cells and bacteria. Intuitively, it seems logical to vent the waste air and heat from FAW toward the floor, away from the surgical site. However, it is now apparent that if the vented waste heat is sufficiently buoyant, it may be possible for it to mobilize contaminated air resident near the floor towards the surgical site, against the downward laminar flow. Supporting evidence for this phenomenon can be seen in a recent research video that captures the effects of forced air warming waste heat-generated air currents on OR ventilation performance.[21]

Air-free alternatives, such as conductive fabric warming (CFW) blankets, have been developed that are comparably effective to FAW for the prevention of surgical hypothermia.[22-28] These alternatives have been shown to have much higher thermal efficiencies than FAW and, therefore, they release only a fraction of the waste heat that FAW use does.[20] As such, there is a need to critically assess the impact of FAW versus air-free alternatives on laminar flow ventilation performance. Thus, we studied the effects of FAW versus CFW on ventilation performance in a laminar flow laboratory representative of an OR environment.

Specifically, we compare the disruptive effects of FAW and CFW waste heat on laminar ventilation performance in a randomized trial using two basic methodologies:

i) Particle counting and tracer smoke to quantify the degree of ventilation disruption; and

ii) Neutrally buoyant helium soap bubbles to visualize airflow patterns.

Methods

Laminar Flow Laboratory Setup

A laminar flow OR environment was constructed for this experiment because most hospitals will not allow the use of tracer smoke or permit an open flame in the OR. The laminar flow laboratory **(Fig 1)** was designed to produce the appropriate ventilation airflow profile and velocities employed in a standard laminar flow OR. To do so, a variable speed HVAC ventilation blower provided a pressurized airflow to a ceiling plenum having a cross section of 2.4 by 2.4 meters. The plenum had a 2 meter vertical height to help diffuse the airflow towards a uniform velocity before reaching the downstream surface of the plenum, which was lined with a HEPA filtration media (Technostat, Hollingsworth and Vose, East Walpole, MA).

The HEPA filtration media acted as a the final diffuser, creating a downward laminar flow over the operating room table (AMSCO Surgical, Model 2080, Mentor, OH). The velocity of the uniform downward airflow could be controlled in the range of 0.0 to 0.5 [m/s] by adjusting the speed of the HVAC blower. For the present experiment, laminar flow disruption was studied at the airflow velocities of 0.3 and 0.5 [m/s] as measured 50 cm downstream of the plenum with a hot wire anemometer (Model HHF42, Omega Engineering, Stanford, CT), airflow rates which corresponded to air changes of 45 and 75 per hour, respectively. The walls of the laboratory were elevated 10 cm off the floor on supports and the HEPA filtered air exited the laboratory around the entire periphery of the room at floor level. When in operation, the laboratory created a downward laminar airflow region having a cross section of 2.4 by 2.4 meters and a positive pressure up to 0.26 cm of H_2O at airflows of 0.5 [m/s].

In the center of this laminar airflow region, a mannequin was laid in a supine position on the operating table and draped in accordance with standard operating procedures for an abdominal incision **(Fig 2)**. Draping consisted of laying a full body surgical drape with no surgical site opening across the mannequin, with the sides of the drape hanging downwards and terminating 50 cm off of the floor. At the head of the table, the drape

was tented to create an ether screen for anesthesia access. The experimental warming treatment was introduced under the drape and applied to the mannequin's legs and was either: 1) a lower body FAW coverlet (Bair Hugger Model 525, Arizant Healthcare, Eden Prairie, MN); or 2) a lower body CFW blanket (Hot Dog Model B103, Augustine Biomedical + Design, Eden Prairie, MN). The CFW blanket turned "off" served as the control. An aerosolized tracer smoke was created outside the laboratory by burning "incense sticks" and delivered by means of a blower and hose delivering 0.028 m^3 per minute of airflow to either: 1) the space under the operating table near the floor, since shed particulate from the surgical staff often accumulate in this location; or 2) between the mannequin's legs, since patient shed particulate is likely to originate and be found in high concentrations in this region. The hose was made sufficiently long to ensure that the particulate tracer had cooled and thermally equilibrated with the environment before introduction.

The CFW blanket and FAW coverlet were powered by un-modified standard controllers (for CFW, Model WC02, Augustine Biomedical + Design; for FAW, Model 750, Arizant Healthcare).

Experimental Design

The experiment involved a randomized and replicated (n=2) 2^{5-1} (res V) fractional factorial design (**Fig 3**) with the blocking identity as the five factor interaction. The experiment assessed changes in tracer particle concentration above the surgical site due to the effect of five 2-level factors defined as: 1) surgeons present or absent, with present defined as two gowned volunteers standing next to the surgical site performing repeated hand movements over the mannequin's abdomen but not touching anything; 2) patient warming modality, having the levels of FAW and CFW; 3) controller heat setting, having the levels of heater "off" (called "ambient" for FAW and "control" for CFW) and heater "on" high heat (43°C) for each modality; 4) ventilation airflow, having levels of 0.3 and 0.5 [m/s]; and 5) tracer smoke location, with levels of floor (staff borne particulate) and legs (patient borne particulate).

Sampling Procedures

Measurements were made in the laminar flow laboratory over a two day period to quantify:

(i) Tracer particle concentrations, which were measured for each experimental treatment at the following locations: 1) under the operating table - defined as 50 cm off the floor under the operating table and between the lower edges of the surgical drape which is the boundary zone between the warm waste FAW air and the air resident near the floor; and 2) above the surgical site - defined as 15 cm above the abdomen of the draped mannequin. Particle concentrations were recorded using two laser particle counters (Handilaz Mini, Particle Measuring Systems, Boulder, CO). Five 0.028 m^3 particle counts (1 minute sampling period each) were taken simultaneously for both measures.

(ii) Supply air temperature exiting the overhead diffuser, which was measured once for each experimental treatment 50 cm below the ceiling diffuser in the center of the air channel using a type "E" thermocouple and meter (Model 52-2 digital thermometer, Fluke, Everett, WA).

Airflow Visualization Procedures

High intensity theater lighting was used to illuminate neutrally buoyant soap bubbles having a 4 mm average diameter. These bubbles were produced by a bubble generator (Sage Action, Ithaca, NY), which utilized a helium-mixed air supply, detergent, and centripetal bubble size classification filter. The bubble generator is specifically designed and validated for the visualization of air currents. The use of neutrally buoyant bubbles for airflow visualization offers a distinct advantage over traditional smoke based methods in that both airflow direction and velocity can be captured in a picture.[17] For photography, a digital camera (D300, Nikon, Melville, NY) was employed with a shutter exposure time set to ¼ of a second.

Assessments

"Tracer penetration of the surgical site" was calculated as the average concentration of particles >0.5 $\mu m/m^3$ detected 15 cm above the surgical site for each experimental treatment; similarly, "under the operating table particle challenge" was calculated as the

concentration of particles >0.5 μm/m^3 detected 50 cm above the floor, under the operating table.

"Tracer penetration of the surgical site" indicates the degree to which tracer-laden under-table air was being mobilized upwards and into the surgical site against the downward laminar airflow.

Statistical Analysis

A Poisson regression model was fitted to the data having tracer penetration of the surgical site as the response and the following 2-level fixed effects as predictors: 1) surgeon ("two present" or "absent"); 2) warming modality ("FAW" or "CFW"); 3) controller heat setting ("off" or "on"); 4) tracer location ("floor" or "legs"); and 5) ventilation airflow ("0.3" or "0.5" [m/s]). Additionally, all two factor interactions were included in the model. Reported values are predicted means (± 95% confidence interval of the mean) for experimental factor combinations based upon maximum likelihood estimates. Likelihood ratio tests were conducted to determine the significance of model parameters. Family wise error rates were not applied to reported confidence intervals of the mean.

The experimental design was robust to model misspecification since main effects are confounded with four factor interactions (likely to be non-significant) and two factor interactions are confounded with three factor interactions (also, likely to be non-significant).

Results

Experimental runs were performed in randomized order representing two replicates of the 16 treatment combinations identified by the experimental design (**Fig 3**). Temperature measurements confirmed a stable laminar ventilation environment having a mean temperature and standard deviation of 19.1°C (±0.9°C). The mean value and standard deviation for under the table particle challenge was 60,000,000 (±17,300,000) for particles ≥ 0.5μm/m^3. Variations from this mean value were observed when the tracer location was changed from the "floor" to "legs", with particle concentrations changing

from 74,000,000 (±7,800,000) to 45,000,000 (±14,800,000) particles ≥ 0.5μm/m^3, respectively. These differences likely resulted from the air sampling location being closer to the tracer release point when it was introduced at the "floor" rather than at the "legs" location. The tracer delivery rate was assumed to be constant throughout the duration of the experiment since the same number of "incense sticks" were always lit in the smoke generation device.

Tracer Penetration of the Surgical Site

All ANOVA model main effects and interactions, with the exception of "airflow" by "controller heat setting", were found to be significant (**Table 1**). As such, the effects of experimental factors on tracer penetration of the surgical site must be considered jointly. To do so, four graphs of predicted means were created showing all experimental factor combinations at fixed levels of airflow and tracer location (**Fig 4**). These groupings are a sensible choice because translation of these results into a clinical setting requires that the clinician: 1) select the appropriate ventilation velocity that best represents their OR environment; and 2) identify the source of airborne contaminant, either patient borne ("leg" location) or staff borne ("floor"), they are most concerned with.

For each fixed level of airflow and tracer location (looking at each graph), differences in tracer penetration of the surgical site appear to be minimal between experimental treatments having "minimal or no waste heat": averaged across the four graphs [particles >0.5μm/m^3 (LCLM, UCLM)], CFW "heat off" (control) showed a mean of 31,800 particles (31,100, 32,800); CFW "heat on" showed a mean of 38,800 particles (38,100, 39,900); and, FAW "ambient" showed a mean of 29,300 particles (28,600, 30,000). In contrast, the use of FAW with the "heat on" added a "waste heat" load to the system, which led to roughly a 30-fold increase in tracer penetration of the surgical site: averaged across the four graphs [particles >0.5μm/m^3 (UCLM, LCLM)], FAW "heat on" showed a mean of 1,040,000 particles (1,031,000, 1,045,000).

The presence of a surgical team, composed of 2 surgeons standing next to the operating table, led to a large increase in tracer penetration of the surgical site *if and only if* a "waste heat" load was present: averaged across the four graphs [particles >0.5μm/m^3 (LCLM, UCLM)], FAW "on high" with 2 surgeons present showed a mean of 3,280,000 particles (X, Y). This is roughly a 90-fold increase in tracer penetration of the laminar flow versus experimental conditions having 2 surgeons present and "minimal or no waste heat" load: averaged across the four graphs [particles >0.5μm/m^3 (LCLM, UCLM)], CFW "heat off" (control) showed a mean of 19,000 particles (X, Y); CFW "heat on" showed a mean of 57,000 particles (X, Y); and, FAW "ambient" showed a mean of 35,000 particles (X, Y).

The presence of 2 surgeons on tracer penetration of the surgical site was also found to be magnified under experimental conditions having higher ventilation airflows: averaged across the four graphs [particles >0.5μm/m^3 (LCLM, UCLM)], experimental treatments having 2 surgeons with ventilation of 0.3 [m/s] showed a mean of 56,500 particles (54,400, 57,200); whereas experimental treatments having 2 surgeons with ventilation of 0.5 [m/s] showed a mean of 144,000 particles (141,600, 146,900).

Waste Heat Generated Convection Currents

The use of FAW on "high heat" generated visible convection currents that mobilized air resident near the floor upward against the downward laminar flow in the space formed between the surgeon's body and the operating table (**Fig 5**). Neutrally buoyant detergent bubbles released at floor level were observed riding this convection current upwards and past the surgeon's head. In contrast, experimental treatments having "minimal or no waste heat" had no mobilizing effect on the neutrally buoyant detergent bubbles. Instead, the bubbles were carried downwards in the laminar flow field towards the floor and away from the surgical site.

Discussion

This study assessed the impact of two different patient warming modalities, FAW and CFW, on laminar ventilation performance in a randomized trial. Vented waste heat from FAW was shown to establish convection currents that rose against the downward laminar

airflow protecting the surgical site from airborne contaminants. Further, the presence of a surgical team also disrupted the downward laminar flow, which magnified the upward flow of the vented waste heat allowing it to rise in the space between the surgeon's body and operating table. In contrast, the use of CFW was shown to have no effect on ventilation performance. The results also showed that waste FAW heat can mobilize air resident near the floor or from between the patient's legs into the surgical site.

The use of neutrally buoyant detergent bubbles ("bubbles") allowed us to visualize the broader airflow dynamics within the laminar flow OR environment and track the movement of air currents carrying tracer particulate. For experimental conditions having "minimal or no waste heat" (FAW "ambient", CFW "off", CFW "high heat"), the bubbles depicted laminar air currents that moved from the ceiling down to the floor. These air currents followed the normal or intended path, sweeping contaminants released from the surgical staff and patient away from the surgical site and towards the floor and then toward the vents. As such, only minimal quantities of tracer particulate (if any) were detected reaching the surgical site in experiments having "minimal or no waste heat" when tracer was introduced at the floor or legs. Thus, the use of CFW was shown to have no affect on laminar ventilation performance.

In contrast, the use of FAW with heat "on" was found to greatly impact the stability of the laminar ventilation environment. OR environments are normally maintained in the range of 20-25°C, meaning that the vented waste heat from FAW use can be as much as 10-20°C in excess of the ambient environment. Such temperature differences impart a natural buoyancy to the vented FAW waste air that causes it to rise upwards towards the surgical site. Within 2 minutes of turning the FAW heat "on", bubbles released near the edge of the drape began floating upwards against the laminar flow in heated currents of air escaping from under the drape edge. Without the presence of a surgical team, the majority of these heated air currents were seen rising up and outwards from the surgical site towards the edges of the room. However, we did observe a small number of these pockets reaching the surgical site, which explains the ≈30-fold elevation detected in

tracer penetration of the surgical site across all experiments having FAW on "high heat" versus controls.

The effects of FAW vented waste heat on laminar ventilation performance were further magnified when a surgical team was present. Bubbles showed FAW vented waste heat to travel from under the drape edge and into the sheltered space between the surgeon's body and operating table. Within this sheltered space, the surgeon's body creates a turbulent wake that disrupts laminar flow and provides a flow stabilizing boundary that favors the formation of localized convection currents.[29] As the waste FAW heat fills this space, hot-air convection currents drive upwards and directly into the surgical site. These convection currents explain the ≈90-fold increase in tracer penetration of the surgical site observed with FAW on "high heat" versus controls. Moreover, increased laminar flow velocity from 0.3 to 0.5 m/s only served to exacerbate the problem. Higher airflow rates appeared to magnify the wake effect of the surgeon's body and the overall turbulence generated within the laminar airflow field. The added turbulence and wake effect, in turn, mobilized larger quantities of tracer laden air from under the operating table into the sheltered space between the surgeon and table. As evidence of this phenomenon, surgical site contaminant concentrations were elevated from ≈50X baseline at 0.3 m/s to ≈100X baseline at 0.5 m/s for conditions involving FAW on "high heat" and 2 surgeons.

Research assessing the effects of thermals, such as surgical lamp or anesthesia equipment waste heat, on ventilation performance has found these effects to be minor[17]. Given that the heat release from surgical lamps occurs in the ventilation field, it is not surprising to find that the heat is quickly diluted and the buoyancy causes it to rise away from the surgical site. Thus it is of minimal importance. Further, lights and surgical equipment generate much less waste heat than FAW.[18] In contrast, FAW use generates a large quantity of vented waste heat that is often released in a sheltered area under the operating table where it cannot be swept away by the ventilation flow. From this location, the buoyancy causes it to rise into the surgical site.

The detection of resident air from the floor and between the patient's legs at the surgical site also suggests the possibility that FAW use may contribute to microbial contaminant mobilization, particularly since air from these locations is often laden with shed skin cells and bacteria. Prior research assessing FAW use and SSI risk has primarily focused on assessing the design of FAW blowers in regards to preventing contamination emissions in the effluent airflow.[11-15] These studies have identified inadequate intake filtration performance as contributing to internal contamination build-up within FAW blowers and the consequent emission of contaminants in the effluent airflow. As a solution to the problem, these authors have generally suggested the addition of distal hose-end HEPA filters for all FAW blowers. However, the results of this study show that even with a hose-end filter, and thus contamination-free FAW waste air, the vented waste heat establishes convection currents that mobilize potentially contaminated air, from the floor or under the surgical drape, into the surgical site. As such, further research is recommended to characterize how the use of FAW affects the mobilization of resident floor contaminates as well as FAW-generated contaminants and if these contaminants elevate the risk of SSI.

A limitation of the present study is that it was performed in a laminar OR ventilation laboratory having two surgeons without the usual flow obstructions present, such as lights and surgical equipment. The inclusion of these factors is likely to magnify the disruptive effects of FAW waste heat and should be studied in a variety of laminar ventilation ORs under appropriate surgical conditions. Further, this study employed smoke tracer particulate that was between 0.5 and 5.0 μm in size, a size corresponding to free floating bacteria and fungi.[30] Additional studies should be carried out with larger tracer particulate representing the size distribution of skin squames, which are generally larger than 5 μm.[31]

Conclusion

This study assessed the effects of two comparably effective patient warming systems, FAW and CFW, on laminar OR ventilation performance in a randomized trial. The effects of FAW waste heat were visually observed to create upward convection currents

between the surgeon's body and operating table, which disrupted laminar ventilation performance. These convection currents were also shown to mobilize contaminated air from the floor and under the surgical drape upwards and into the surgical site. In contrast, CFW had no effect on ventilation performance. Until the SSI risks resulting from laminar flow ventilation disruption by FAW can be further evaluated, the use of air-free patient warming alternatives might be recommended for contamination sensitive procedures carried out in laminar flow ORs.

Table 1. Significance of Poisson model fixed effects.

Main Effects, *P_value*	
Airflow (0.3, 0.5 [m/s])	<0.0001
Surgeon (absent, 2 present)	<0.0001
Controller heat setting (on, off)	<0.0001
Device (CFW, FAW)	<0.0001
Tracer (floor, legs)	<0.0001
Two Factor Interactions, *P_value*	
Airflow X Surgeon	<0.0001
Airflow X Device	0.0105
Airflow X Controller heat setting	0.0598
Airflow X Tracer	<0.0001
Surgeon X Device	<0.0001
Surgeon X Controller heat setting	<0.0001
Surgeon X Tracer	<0.0001
Device X Controller heat setting	<0.0001
Device X Tracer	<0.0001
Controller heat setting X Tracer	<0.0001

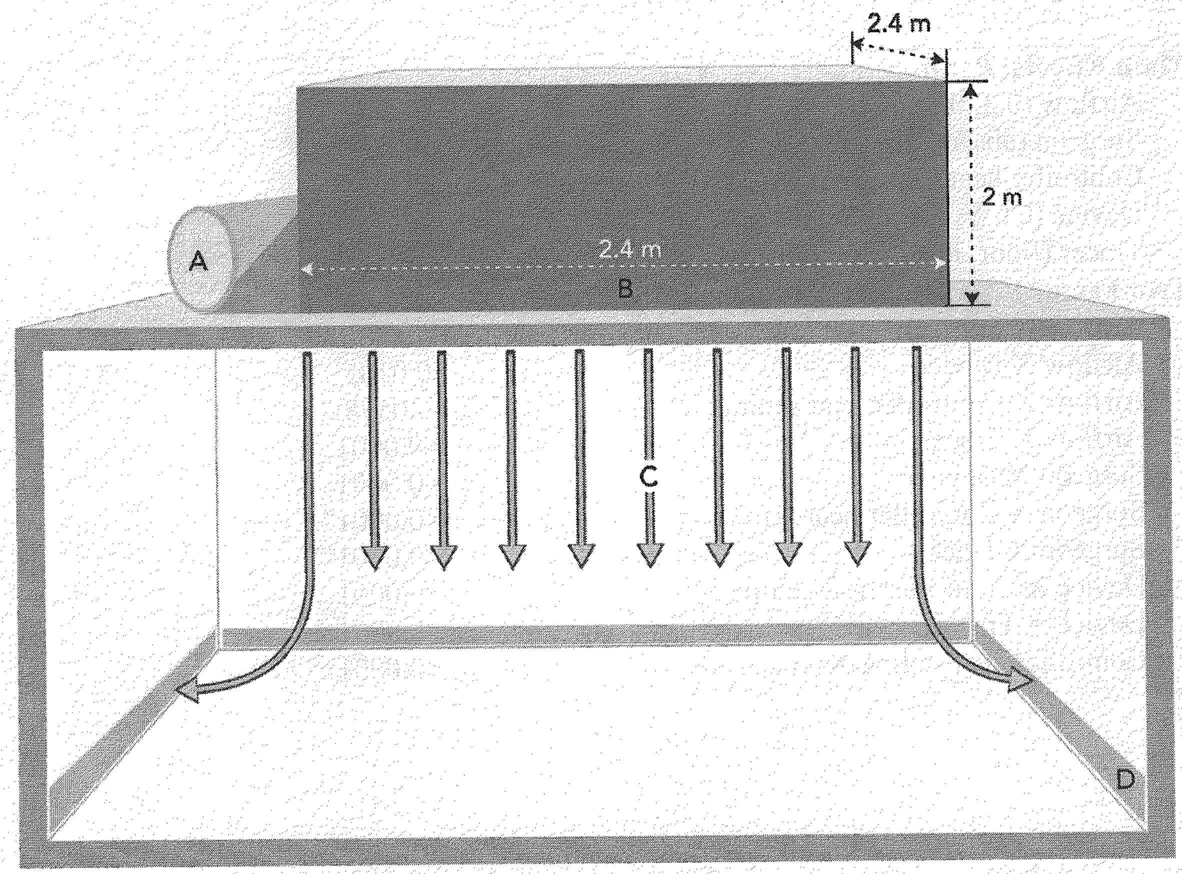

Figure 1: Laminar flow laboratory, having a variable speed HVAC ventilation blower (A) that pressurizes an air distribution plenum (B). The pressurized airflow enters the laboratory through the lower plenum surface and is filtered as it passes through a layer of HEPA filtration media. The filtered airflow (C) enters the laboratory in a downward fashion at a uniform velocity of 0.0 to 0.5 m/s depending on blower speed. Waste airflow is exhausted around the entire periphery of the room (D).

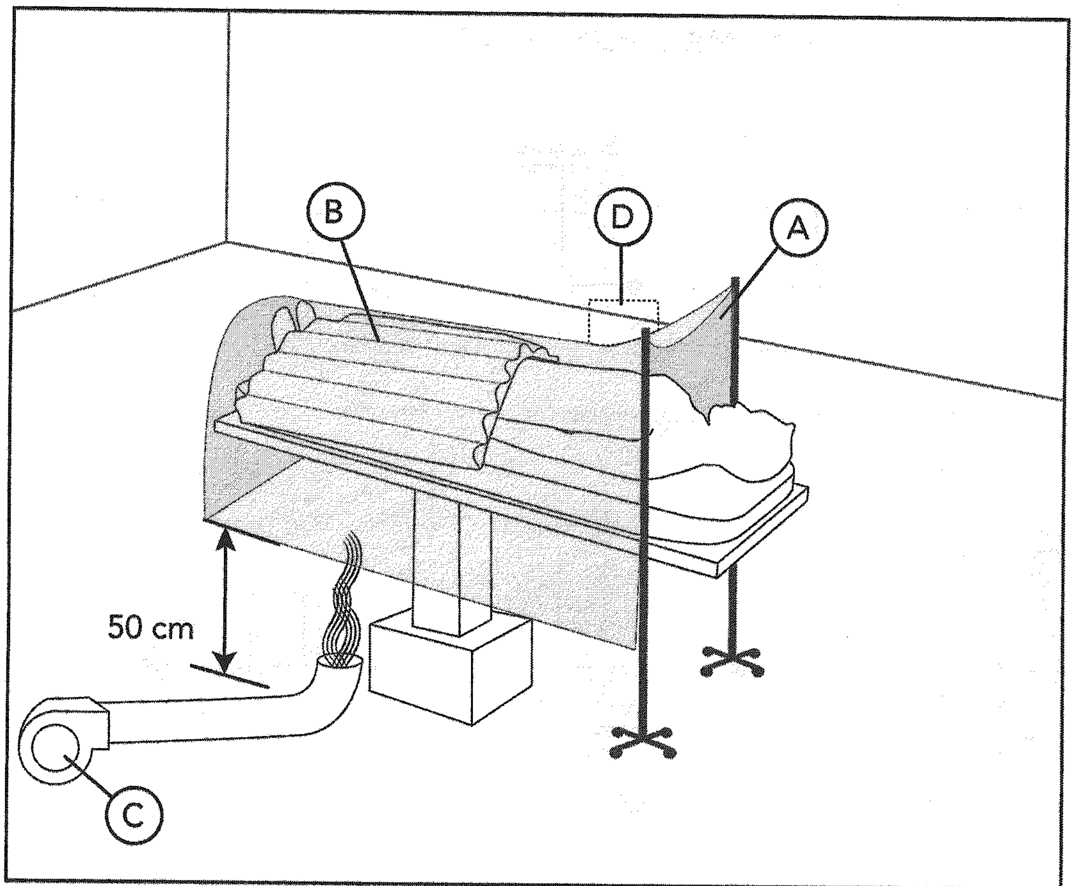

Figure 2: Experimental setup in center of laminar flow laboratory with adult mannequin in the supine position, showing: (A) surgical draping; (B) experimental warming treatment (conductive fabric warming or forced air warming); (C) blower conveying tracer particle challenge (introduced under drape at floor level or between the patients legs); and (D) surgical site particle sampling location.

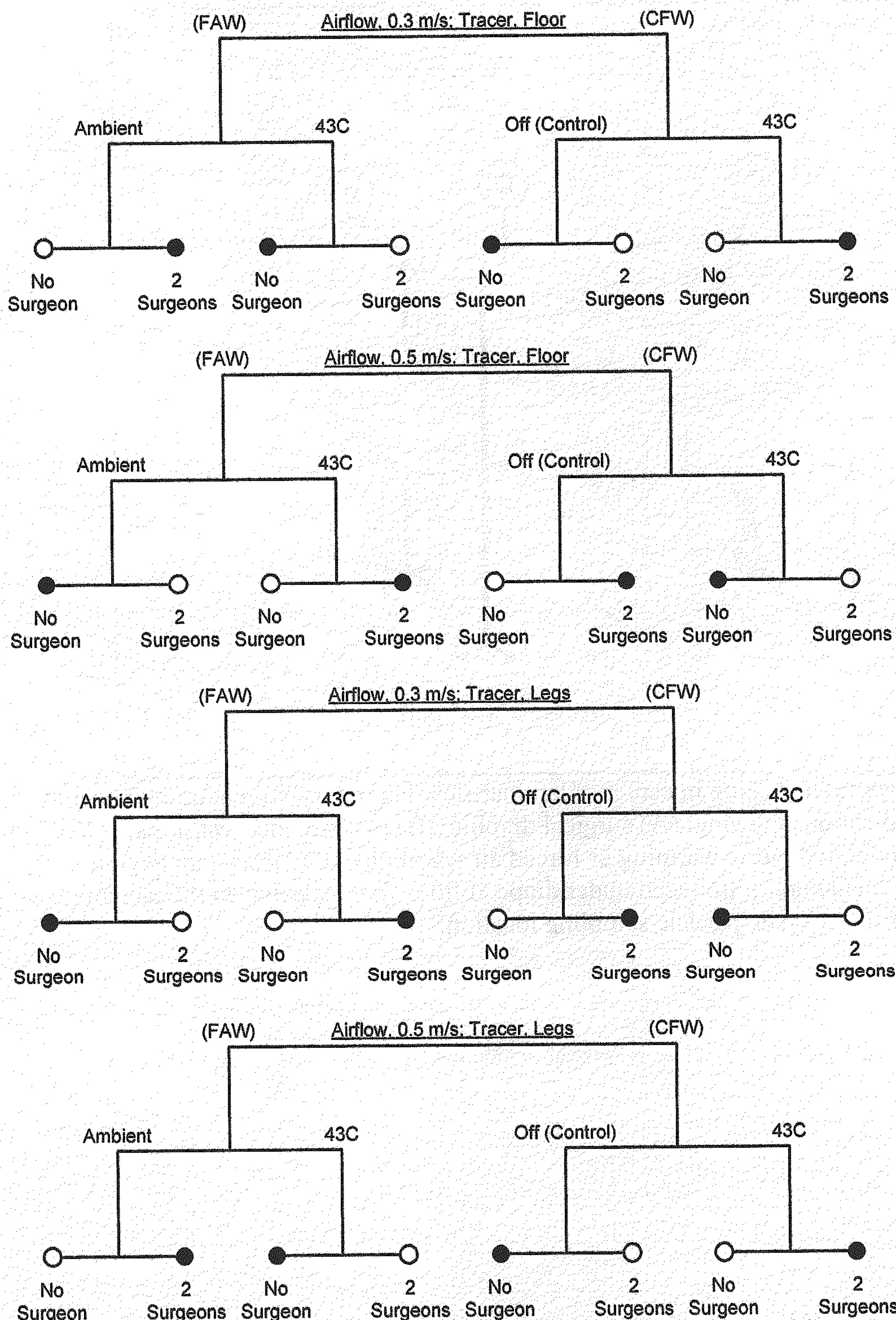

Figure 3: Experimental design: Randomized and replicated (n=2) 2^{5-1} (resolution V) fractional factorial design. Design is grouped by experimental factors of air flow and tracer location for display purposes only; the entire design was administered and randomized in an un-grouped fashion. Open circles represent excluded data points.

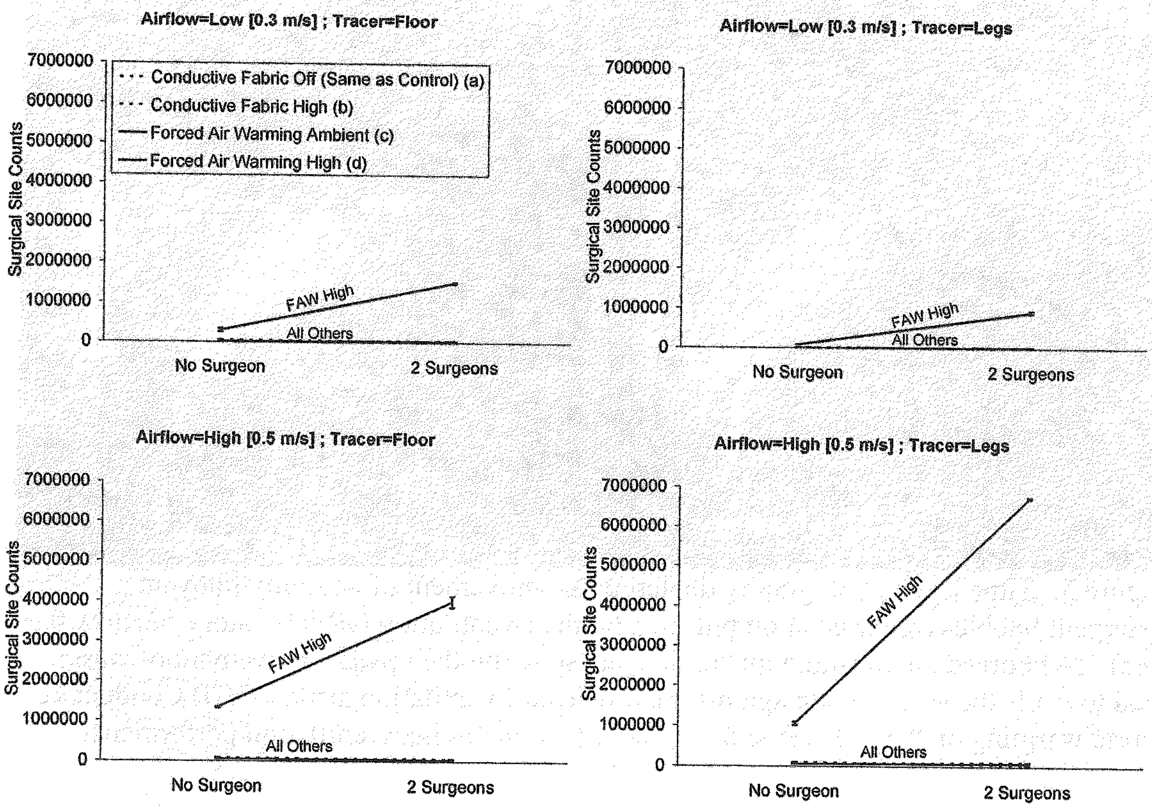

Figure 4: Predicted tracer penetration of the surgical site [particles >0.5 μm/m^3] (± 95% confidence interval of the mean) based upon maximum likelihood estimates for experimental factor combinations. Experimental factor combinations are grouped at fixed levels of airflow and tracer location.

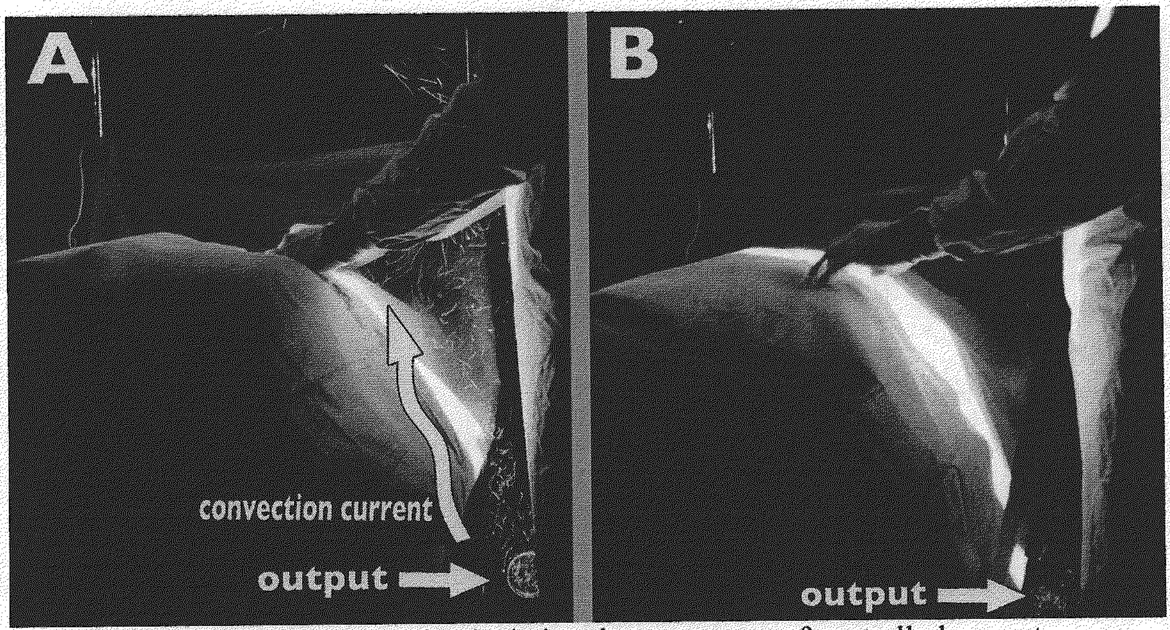

Figure 5: Time lapse photography depicting the movement of neutrally buoyant detergent bubbles (released at output) in a laminar ventilation OR laboratory (airflow 0.5 m/s). (A) Forced air warming on "high heat" showing the upward movement of waste heat towards the surgical site against the downward ventilation airflow. (B) Conductive fabric warming on "high heat" showing no effect on laminar ventilation performance.

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C

A message to healthcare professionals[1-6]

Science, Guidelines and Users Agree: Forced Air Warming is Technology You Can Trust

Forced air warming is a clinically proven and trusted patient warming technology with 125 million patients warmed worldwide, a wealth of clinical research (including more than 170 published papers) and multiple international recommendations supporting its use. The evidence behind forced air warming's safety and efficacy is overwhelming.[1-6]

Despite this, some manufacturers of electric blankets, pads and other conductive warming modalities are attempting to plant fears about the safety of forced air warming. One has even claimed that the country's most prominent method of surgical warming may be contributing to surgical site infections (SSIs) by "blowing air" around the operating theatre, or disrupting laminar air flow.

It is time to put an end to these baseless claims about forced air warming and set the record straight.

These allegations contradict the extensive research reviewed by the National Institute for Health and Clinical Excellence (NICE) during the development of its *Clinical Guideline 65: Management of inadvertent perioperative hypothermia in adults*. This guideline states that forced air warming does not present an infection risk[7], and specifically cited forced air warming as a proven tool for the reduction of SSIs.

Published research papers show that the use of forced air warming does not increase either the risk of wound contamination in the operating theatre or bacterial contamination of operating theatres.[8-12] Research published in the September 2009 issue of the *Journal of Hospital Infection* found that warming with the Bair Hugger® forced air warming system during orthopaedic surgery does not present an infection risk.[11] In fact, when tested during actual surgical conditions, data show a decrease in the bacterial counts around the patient and in the operating theatre when forced air warming was used.[10,11]

Competitors offering conductive warming products have also recently made statements regarding forced air warming's performance in laminar flow conditions. While simple logic makes it clear that forced air warming has no impact on laminar conditions, science also supports this. A forced air warming blanket delivers less than one percent of the airflow of a laminar flow system and therefore is unable to affect laminar flow ventilation systems.[13]

Rely on Evidence and Experience

Maintaining normothermia with forced air warming has been demonstrated to reduce costly and serious complications associated with inadvertent hypothermia, including SSIs. The evidence is solid.

For more information on the evidence of forced air warming please visit **www.arizant.co.uk** or contact us directly at +44 (0) 1924 200550.

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Arizant

V

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134 Industry Information: www.fda.gov/oc/industry	11/30/2009 - 01/06/2010* FEI NUMBER 2183725

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gary R. Maharaj, President & CEO

FIRM NAME	STREET ADDRESS
Arizant Inc	10353 W 70th St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Eden Prairie, MN 55344	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury.

Specifically, the following adverse event was not filed as an MDR:

CALL 63505 dated 04/13/06 states, "Female pt sustained 2nd degree burn to breasts and surrounding soft tissue after approx 1 hr knee scope porcedure [*sic*] in the OR with Bair Paws 84001 or 84201 OR gown and 505 warming unit (S/N 69412)." The patient was subsequently treated in the ER.

OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, the following malfunction complaints were not filed as MDRs:

Complaint	Reported Event
CALL 73378 dated 07/30/07	"Heater in unit is not functioning, does not heat" The patient exhibited disseminated intravascular coagulation (DIC) as a result of lowered body temperature which led to excessive bleeding.
CALL 76774 dated 01/02/08	Physician stated the warming unit was found to be operating improperly resulting in two burn incidents. The event was reported confirmed by the biomed group.

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CALL 92646/92618 dated 08/20/09 Pt injury on or about 8/17 was reported by a healthcare professional when the warming unit hose partially separated from the blanket. Warming continued and "pt sustained redness or a burn".

CALL 66624 dated 09/14/06 Unit caught fire while in use on the patient's bed. The device was immediately unplugged and removed from the stretcher.

CALL 81669 dated 07/15/08 Unit caught fire in the OR down at the power cord. No patient was involved.

OBSERVATION 3

The written MDR Procedure does not include an internal system which provides for the timely and effective evaluation of events that may be subject to medical device reporting requirements.

Specifically, Procedure No. 140500, Adverse Event/Injury Reporting, Rev G does not provide guidance for determining when an event meets the criteria for reporting. Effective evaluation of each injury and malfunction complaint has not been implemented (as is demonstrated by Observations 1 &2).

In addition, there is no documented evaluation to determine the reportability for the following injury complaints:

Complaint **Reported Event**

CALL 90142 dated 05/22/09 21 mo male child received 2nd - 3rd degree burns on left ear. Arizant manager stated in July 2009 that the "staff concluded that the incident was not due to the warmer or Bair Hugger blanket".

CALL 79475 dated 04/16/08 Reported 2nd - 3rd degree burn to a pt. during a two hour procedure. In August 2008, the injury was said to have been 1st degree burns.

CALL 95129 dated 11/09/09 11 incidents of pt burns to the mid back during ENT surgeries. "Blistering, followed by sloughing of the surface layers occured 12+ hours later". Current patient conditions unknown.

CALL 85323 dated 11/25/08 Patient burned on lateral thighs during abdominoplasty and breast aug. In Feburary 2009, Arizant was made aware the blanket did not cause the burns via email.

OBSERVATION 4

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically, in January 2007, a Service Bulletin with enclosed "Blower Inspection Model 850 Warming Unit" instructions was sent to Arizant Bair Paws Model 850 customers. The service bulletin asked users to inspect their Model 850 Bair Paws units for the sagging heater coil and subsequently attach the provided 'Inspected' sticker on each unit. The bulletin also

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advised customers to discontinue use of the units found to have continuously running motors and return these units to Arizant. Arizant would then send the consignee a replacement unit.

OBSERVATION 5

Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary.

Specifically, customer complaint investigations or justification for not investigating are not documented for the following complaints:

CALL	Date	Reported Event
85743	12/12/08	Burned controller- "Says the controller is all carboned up on the bottom side. The carbon is due to high heat."
89918	05/13/09	Exchange, not heating, no fault code- "Elbow sensor defective".
90025	05/19/09	Kink in cassette caused leak
91168	06/30/09	Exchange, fan runs continuously
91451	07/10/09	"Exchange, burn smell after turn on, then smoke"

The information provided for each reported event is limited.

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Observation Annotations

Observation 1: Promised to correct within 15 days.
Observation 2: Promised to correct within 15 days.
Observation 3: Reported corrected, not verified.
Observation 4: Corrected and verified.
Observation 5: Reported corrected, not verified.

*** DATES OF INSPECTION:**
11/30/2009(Mon), 12/02/2009(Wed), 12/03/2009(Thu), 12/08/2009(Tue), 12/18/2009(Fri), 12/29/2009(Tue), 01/06/2010(Wed)

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